

Exhibit 107

'57-09-18 00:34 A.P.

P.1

ALFRED P. WEHNER, D.M.D., Sc.D., CAND. MED.
DIPLOMATE, ACADEMY OF TOXICOLOGICAL SCIENCES
312 SAINT STREET
RICHLAND, WASHINGTON 99352

9/17/97

Mr. Michael R. Chudkowski
Manager, Preclinical Toxicology
J&J Consumer Products, Inc.
Skillman, NJ 08558-9418

Dear Mike:

There is a German saying which translates as follows:

"A true friend is not he who beguiles you with flattery
but he who discloses to you your mistakes
before your enemies discover them."

In this spirit I would like to volunteer a critique of the three CTFA response statements which you faxed me on September 11. Some of the wording leaves CTFA wide open to counter-attack. The most harmless response statement of the three is the one dated July 1, 1992. It does not give the names of the authors and the title of the paper to which the response is being made. More important, I believe that different and/or additional more powerful statements along the lines of my critique faxed to Jerry McEwen, as far as applicable to the situation in 1992, would have put CTFA in a more advantageous tactical position. Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not trans-late (sic!) through the cervix to the uterine cavity and beyond" does not address the problem, does not refute these findings, and therefore does not serve CTFA's best interest. All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk." This statement is outright false. All an Epstein, a Kennedy, or one of their aides knowledgeable in matters talc, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0873 Fax 509/375-5693

Plaintiff's Exhibit
No.

P-20

J&J-0115053

'97-09-18 00:35 A.P.

P.2

Here, too, I believe that more powerful and better defensible arguments could and should have been made on behalf of the industry.

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper, Debra Heller, and others. What the workshop panel did conclude was that (1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconclusive, (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments (plus some of those along the lines of my fax to Rich) instead of questionable mush that leaves one vulnerable to counterattack? The following sentence states: "In addition there is no basis to conclude that talc is capable of migrating to the ovaries...". I submit that several reports, independently describing talc particles in/on ovarian tissue, along with other suggestive evidence (questionable as some of it might be) does provide a basis for just such a conclusion. My point is that such a complex and vexing issue cannot be credibly dismissed with one sweeping statement without any documenting references.

Mike, I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent. As a consultant on a retainer I feel obligated to proactively act in the best interest of my client at all times, not only when I am approached with a specific assignment. This consideration alone motivated me to spend the time to bring my thoughts on this matter to your attention. I trust that in the process I did not step on anybody's toes.

Best regards

AL

J&J-0115054

Exhibit 108

C · T · F · A

Representing the personal care products industry

*E. Edward Kavanaugh
President*

DRAFT MINUTES

TALC INTERESTED PARTY TASK FORCE

CTFA
Main Conference Room
1101 17th Street, N.W., Suite 300
Washington, DC 20036

Plaintiff's Exhibit
No.

P-14

July 21, 1993

A meeting of the Talc Interested Party Task Force was held at CTFA on Wednesday, July 21, 1993 beginning at 10:00 a.m. Those in attendance were:

Dr. Laureen MacEachern - COLGATE-PALMOLIVE
Ms. Kate Trammell - MAYBELLINE
Mr. William Ashton - JOHNSON & JOHNSON (Guest)
Mr. Mike Chudkowski - JOHNSON & JOHNSON
Mr. Richard Zazenski - LUZENAC AMERICA
Dr. Martin Roddy - NOXELL
Ms. Marjorie McTernan - JOHNSON & JOHNSON (Guest)
Dr. Stephen Gettings - CTFA (Liaison)

I. OPENING REMARKS

1. SGettings opened the meeting and apologized for calling it at such short notice. He noted that the purpose of the meeting was to discuss the outcome of a meeting SGettings held with members of the Planning Committee of the International Society of Regulatory Toxicology & Pharmacology (IS RTP), held at the ToxForum meeting on July 14th, 1993. The minutes of the last meeting were approved with no changes.

II. INFORMATION EXCHANGE/GENERAL DISCUSSION

1. SGettings noted that ISTRP have been asked by FDA to organize a 1-2 day symposium on talc safety and related issues (93-TA-10). The Task Force was alerted as to this possibility in February, 1993 (93-TA-07).
2. At the IS RTP Planning Committee meeting SGettings was

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apprised of the following:

The intended target audience are regulatory specialists, toxicologists, food/drug/cosmetic/medical device manufacturers, academicians and medical professionals. At least 100 attendees are anticipated.

From the meeting, FDA hope to gain insight into the relevance of recent toxicological and epidemiological studies to the safety of regulated products. FDA would like participants to address not only the validity of experimental approach but also risk "under conditions of use." FDA does not anticipate that they will be able to develop a regulatory decision from this program alone.

The meeting will be held in the Washington, DC area, possibly at the NIH auditorium. It will be scheduled for late fall (probably November) or for early 1994 (January).

The symposium will relate principally to ingredient use and safety as it applies to consumer products. (FDA anticipate that scientific studies relating to occupational uses of talc will contribute to the program as it relates to consumer products). Relative to OTC drug use of talc, FDA feel that someone from USP should at least serve on the panel for discussion and possibly make a presentation on USP specifications. Apparently, the OTC group thinks there should be a discussion of product labeling as it applies to OTC products, i.e., diaper rash could be discussed for adequacy and possible suggestions. FDA feel that this portion of the program would be useful in assessing whether or not the current USP specifications are adequate.

The proceedings of the symposium will probably be published (probably as a meeting summary, by rapporteurs).

FDA is budgeting \$10,000 as financial contribution to the effort; industry has been asked to contribute \$20,000; the remainder will be provided by IS RTP.

The anticipated format is to have some sort of "expert panel" in attendance throughout the meeting. FDA suggest that someone from industry (possibly a member of the CIR Expert Panel) and a consumer representative be invited to sit on the panel. Following the presentations, FDA would like to have ample time for discussions from the floor. The discussion will be led by members of the panel.

3. The following agenda has been proposed following discussions between IS RTP and FDA:

DAY 1 - The first day of the symposium will concentrate on inhalation health considerations, and will take the following format:

Introduction - introduce the topic, present the reasons for holding the symposium and provide some background about studies conducted on the safety of talc (historical perspective). IS RTP have been asked to identify someone who can serve in this capacity.

Manufacture of talc - To discuss (1) how, and where, it is obtained (mineral sources), (2) specifications for talc as used in different products, and (3) quality control including steps to control and monitor asbestos contamination. FDA stress that it is important for this presentation to describe the "specifications" for the material that is actually used in different products (i.e., particle size, impurities, etc). CTFA has been asked to identify a suitable speaker.

Uses of talc in different FDA-regulated products - Specifically, what are the requirements for the use of talc in foods, drugs, cosmetics and medical devices and why they are critical. (FDA suggest that this presentation may be combined with the previous one).

Regulatory status of talc in the different product categories - This topic will be discussed by one (or more) FDA officials.

Health Perspectives - Presentation and critique of the NTP inhalation study by various presenters (eg., Oberdorster, Goodman etc).

Panel/Floor discussion

DAY 2 - The second day will primarily cover ovarian cancer and talc, but epidermatology as it relates to inhalation exposure with will also be discussed.

Introduction - historical overview of the various epidemiology studies on talc (possibly in 2 parts):

- a. Epidemiology studies of occupational exposures (inhalation).
- b. Epidemiology studies on ovarian cancer.

Risk factors in ovarian cancer

Harlow's Epidemiology studies of ovarian cancer and perineal exposure.

Meta-Analysis - Discussion of the pros and cons of meta-analysis as a general statistical tool in measuring correlations in epidemiology studies.

Panel/Floor discussion

Moderator wrap-up and close

III. ACTION/NEXT STEPS

1. The Task Force agreed that it was clear that the ISTRP meeting will be held irrespective of industry input, but that such input was important. The Task Force agreed that it was important that, as industry's representative, SGettings continue to participate at the ISRTP Planning Committee meetings and to offer advice and suggestions as outlined by the Task Force.
2. The Task Force agreed that the level of sponsorship requested by industry was not prohibitive. CTFA will send out commitment forms requesting total sponsorship from the Task Force of \$20,000 (depending upon the number of participants, as low as \$1,000 per company).
3. The Task Force agreed that Dr. Bruce Semple (formerly of J&J, now with P&G) should be approached and asked to represent industry on the Panel (both days of the meeting).
4. The Task Force agreed that a representative of one of the talc suppliers should make a presentation on (1) the production, processing and quality control of talc manufacturer; and (2) particle size and specifications for different product applications. RZazenski agreed to provide a presentation outline and a suggested speaker within the next few days. The Task Force agreed that all speakers will be representing the industry and that the Task Force will approve the contact of each industry presentation.
5. The Task Force agreed that a representative of a finished-product manufacturers should make a presentation on consumer use/risk assessment of cosmetic products containing talc. SGettings will get clarification on whether other speakers will address similar issues as they relate to other talc uses. The Task Force suggested that BSemple would again be the most appropriate industry representative. The Task Force agreed to begin assembling data which might form the basis of such a presentation. It was noted that some of this information (on particle size and product notices) had previously been requested by FDA and that the Task Force had not been successful in collecting such information. WAShton

agreed to review, in particular, J&J's published data on exposure to talc. RZazenski noted that a lot of useful information could be derived from the report prepared by JKalse for the Task Force. LMacEachern noted the presentation should reference recent studies on talc (93-TA-12). LMacEachern noted that the presentation should emphasize the safety of talc use.

6. The Task Force agreed to review available information on occupational exposure from inhalation, and to discuss this issue at a follow-up meeting.
7. The Task Force agreed that both Dr. Oberdorster and Dr. Wehner (both co-authors of the BEC Report) should be proposed as speakers (on lung overload mechanisms and the biological implausibility of ovarian cancer from talc exposure, respectively). The Task Force agreed that industry should arrange for their attendance (at cost), even if they are not selected as speakers. It was also suggested that the Task Force may wish to arrange for the attendance of other consultants if necessary.

IV. ADJOURNMENT/NEXT MEETING

1. It was noted that SGettings next meets with ISRTP in early August. The Task Force agreed to hold a follow-up conference call within the next few days and to arrange a Task Force meeting in early September.
2. There being no further business, the meeting was adjourned.

Respectfully submitted,

Formulate Question/Answers regarding anything on talc
Stephen D. Gettings, Ph.D., D.A.B.T.
CTFA

IAEC - inadequate evidence to show carcinogenicity

— literature survey — publication —

ISRP - Industry Friendly

Exposure data into presentation - Consumer Use

Spinks question from panel or audience. Need experts to address questions.
Langer - IAEC comm. Brooklyn Coll.

— JWRs for search

— Press release summary —

— Mack Ross (Hazardous Survey)

Silica - issue cosmetic talc (B.P.) that contain crystalline silica that (0.1%) that is a carcinogen. Industrial use - labeling req't if > 0.1% silica concentration.

Exhibit 109



FEB 13 '98 02:37PM CTFA1

P.1/3

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

MEMORANDUM

E. EDWARD KAVANAUGH
PRESIDENT

DATE: February 13, 1998
TO: TALC INTERESTED PARTY TASK FORCE
FROM: Pandora Dennis
Administrative Assistant - Science

Please deliver this and the following page(s) to the corresponding individual in your company.
Thank you.

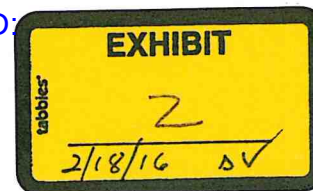
Ms. Debra Ambrose/POLAR MINERALS/(812) 838-4744
Mr. William Ashton/JOHNSON & JOHNSON/(908) 874-1254
Ms. Donna Beach/COSMAIR/(908) 499-2929
Dr. Daniel Briggs/PROCTER & GAMBLE/(513) 626-4399
Mr. Michael Chudkowski/JOHNSON & JOHNSON/(908) 874-1254
Mr. Shawn Hays/POLAR MINTERALS/(404) 934-4376
Dr. John Hopkins/JOHNSON & JOHNSON/(908) 874-1155
Mr. Daniel Johnson/COMBE INCORPORATED/(914) 694-1585
Mr. John Kelse/RT VANDERBILT COMPANY/(203) 853-1452
Mr. Louis Kotyuk/WHITTAKER, CLARK & DANIELS/(800) 833-8139
Mr. Mike Larson/MINERALS TECHNOLOGIES/(212) 878-1804
Dr. Laurie Pan/MARY KAY COSMETICS/(214) 905-6799
Dr. Steve Pennisi/COMBE INCORPORATED/(914) 694-1585
Mr. Thomas Pallone/ALBERTO-CULVER/(708) 450-3067
Dr. Thomas Re/BRISTOL-MYERS/(908) 851-6250
Ms. Janice Rogers/GILLETTE/(301) 590-1535
Dr. Bruce Semple/PROCTER & GAMBLE/(513) 626-2977
Dr. Tracey Spriggs/COLGATE-PALMOLIVE/(908) 878-7844
Ms. Elaine Stern/HELENE CURTIS/(312) 384-3539
Ms. Joan Thomas/CTPA/(011) 441714938061
Dr. Maureen Toulon/AVON/(914) 369-2898
Mr. Richard Zazenski/LUZENAC AMERICA/(303) 643-0446

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202.331.1770 FAX 202.331.1969
<http://www.ctfa.org>

SECURING THE INDUSTRY'S FUTURE SINCE 1894

Exhibit 130



TITLE: Talc IP - Revenue Received
 GENERAL LEDGER ACCOUNT: #25078
 DATE INITIATED: 08/17/92

PARTICIPANTS:	1992	1993	1994	1997	2000	2001	2005	2008	2009	Total
Alberto-Culver				500						500
Avon Products	5,000	2,000	894		10,000	2,000				19,894
Bristol-Myers / Clairol				500	6,000	1,500				8,000
Carter-Wallace, Inc.	5,000									5,000
Colgate-Palmolive	5,000	2,000	894	500						8,394
Combe Inc.				500						500
Cosmair, Inc.	5,000	1,500	894	500	1,000					8,894
Estee Lauder, Inc.	5,000									5,000
Helene Curtis / Unilever	5,000	1,500	894	500	31,000	6,500				45,394
Johnson & Johnson	5,000	2,000	9,310	500	151,000	7,500	15,000			190,310
L'Oreal					10,000	2,500			2,500	15,000
Luzenac America	5,000	2,000	894	500	31,000	7,500			2,500	49,394
Mary Kay Cosmetics	5,000	1,000	894	500	1,000	500				8,894
Maybelline, Inc.	5,000	1,500	894							7,394
Pfizer/Minterals Tech.	5,000	1,500	1,126	500		500				8,626
Polar Minerals				500	1,000	500				2,000
Procter & Gamble (incl Noxell)	5,000	2,000	894	500	1,000					9,394
Schering-Plough Corp.	5,000	1,500	894							7,394
US Cosmetics Corp.	5,000			500						5,500
R. T. Vanderbilt	5,000	1,500	894	500	1,000					8,894
Whittaker, Clark & Dan.	5,000	1,000	894	500	1,000					8,394
American Westmin	5,000	1,000	894							6,894
Mary Kay Cosmetics								2,500		2,500
Procter & Gamble								2,500		2,500
Revlon								2,500		2,500
The Dial Corp									2,500	2,500
	85,000.00	22,000.00	21,164.00	7,500.00	245,000.00	29,000.00	15,000.00	7,500.00	7,500.00	439,664.00

Exhibit 111

Luzenac America

Profile

- 4 Talc Mines & 8 Mills in North America
- 500,000 TPY
- \$85 MM Sales
- Primary Markets
 - Paper
 - Polymers
 - Paint & Coatings
 - Personal Care (i.e. J&J Baby Powder)

-1

Protected Document – Subject to Protective Order

LUZ022044

1 of 7

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Regulatory Issue

National Toxicology Program (NTP)

- Coordinates Interagency Toxicological Testing
- Publishes Report on Carcinogens (RoC)
- Minimal Threshold for Carcinogenic Listing
- Listing Triggers OSHA and Prop 65 Labeling
- Conducted Talc Inhalation Study on Rodents
- Nominated Talc for Review in 2000

-2

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LUZ022045

NTP Listing Consequences

- Immediate Loss of Personal Care Market
 - \$10,000,000 in Year 1
- Deterioration of all Markets due to Labeling
 - 20 to 50% of remaining sales year 3
- Regulated as a Carcinogen Worldwide
- Talc Litigation likely to Proliferate

Talc Health Issues

- Risk Factor in Ovarian Cancer
 - Perineal dusting by women
 - No causal explanation
- 1992 NTP Rodent Study
 - Lung tumors in female rats
 - Lung overload phenomenon
- Association with Asbestos
 - Long-held public perception
 - Chemical similarity

NTP Talc Review Summary

- Review Group 1 voted 6-1 *to List* Talc
 - Cited ovarian studies and NTP Rodent study
- Review Group 2 voted 7-1 *to List* Talc
 - Cited ovarian studies and NTP Rodent study
- BSC Subcommittee Voted 7-3 *Not to List* Talc
 - Influenced by industry comments and criticisms of NTP Report on Talc
- NTP Exe. Committee Defers Vote on Talc
 - Remands issue back to NTP reviewers

Luzenac Defense Strategies

- Unite Behind the Cosmetic, Toiletry & Fragrance Association (CTFA)
- Engage Services of the "Center for Regulatory Effectiveness (CRE)"
- Aggressive Corporate Position

OUTLOOK

- Deferral Due to "Fatal Flaws" in Draft Report
- Temporary "Reprieve" for 2-3 Years
- Insist Upon the Need for Additional Studies
- Updates on Gertig et al. Study of 76,630 U.S. Women - No Increased Risk with Talc Usage
- Re-examine Prior Epidemiology Studies - Negative Dose Response?
- IARC Re-examination of Talc a Possibility

Exhibit 112



Representing the personal care products industry

92-SE-328

92-SAC-24

E. Edward Kavanaugh
President

MEMORANDUM

TO: Scientific Advisory Committee

FROM: G.N. McEwen, Jr., Ph.D., J.D.
Vice President - Science

DATE: July 17, 1992

SUBJ: TALC SAFETY INTERESTED PARTY

The conclusions in two recent studies question the safety of cosmetic grade talc. A draft report of one study, involving daily, lifetime inhalation of massive amounts of talc in rats and mice, concludes there is clear evidence that talc is a carcinogen for female rats, and some evidence that it is a carcinogen for male rats. There was no evidence of carcinogenicity in male or female mice. The other study concludes that there is an association between talc use in the perineal area and ovarian cancer in women. CTFA will provide copies of these reports upon request.

Although CTFA is convinced that these studies do not suggest any hazard from normal use or foreseeable misuse of personal-care products or cosmetics containing talc, such reports may have wide implications for classification and characterization of talc by various regulatory agencies, including OSHA, FDA, and California's Office of Environmental Health Hazard Assessment, responsible for listing substances for Proposition 65.

CTFA has instituted an Interested Party Task Force to address these studies. The Task Force is developing a strategy to defend the continued safe use of talc, and is open to those companies willing to provide financial support for this activity. For further information on how to join the Task Force, please contact Dr. Stephen Gettings, Director, Toxicology, CTFA.

GNM/pcl
cc: Scientific Advisory
Executive Committee

The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, N.W. • Suite 300 • Washington, D.C. 20036 • (202) 331-1770 • Fax (202) 331-1969

Plaintiff's Exhibit
No.

P-122

Exhibit 113

CALL REPORT
Luzenac America

Date: 11/8/93 Regional Manager: J. A. Tracy
Date of Call: 11/8/93 Accompanied By: _____

Cust Name: Carter Wallace Cust#: 05258/0000
City & State: Trenton, NJ Industry Code: 05:001
Contacts: Deborah Richardson, Purchasing Agent

Prod#: 11234 Descrip: Vertal 1500USP Qty: 200TPY Price: _____

Comp#1: DeGussa Prod: Hydrated silica Qty: _____ Price: _____
Comp#2: _____ Prod: _____ Qty: _____ Price: _____

PRODUCT APPLICATION: Dusting of latex rubber condoms.

OBJECTIVE: Find out the status of the replacement of talc, and discuss the Johnson plant closing.

SUMMARY: Debbie said that they have switched from talc to hydrated silica that they get from DeGussa. Huber is another approved supplier. She said that the silica is so light and fluffy that they have built a closed dusting system to contain the dust. I asked her if they were not concerned about the use of silica. She said they were, but felt that the only problem was with respirable silica. Their closed system they feel is sufficient protection for their workers.

She said that they were pleased with the performance of talc, but were concerned because a CTFA report in July 1992 said that there was suspicion that talc could cause ovarian cancer. Although the report didn't say that it was a cause, Carter Wallace is concerned about future litigation.

Debbie said that if silica becomes a problem, they might look at talc again.

ACTION REQUIRED: No action required.

Exhibit 114

January 2, 2002

Principal Argument for Adopting Luzenac America's NTP Strategy

We engaged the council of the Center for Regulatory Effectiveness ("CRE") in November 2000 for the purpose of providing us direct assistance in developing a business strategy to challenge the NTP talc review. CRE 'knows' NTP. CRE knows many of the individuals personally – most importantly, the key decision-makers. They know how NTP operates, both technically and politically. CRE knows how NTP 'values' the significance of published human and animal studies. CRE knows the influential people from the other agencies who get involved in the review process. Simply put, CRE possesses the knowledge and experience to help us effectively mount a strategic challenge to the NTP talc review.

From the beginning, CRE has recommended that we adopt an aggressive (professional) approach with NTP. Our technical (and legal) arguments have alternated between Luzenac and CRE letterhead - designed to maximize the intended effect.

Presently, CRE believes the request for by Dr. Olden (NTP Director) presents us with an opportunity to 'proactively' submit a detailed literature research paper that not only directly addresses the unresolved issues (mineralogy), but also other controversial issues that we anticipate will (or should) resurface (epidemiology, causation, consistency of results). It affords us the opportunity to initiate the agenda for discussions with NTP.

To reject their recommendations in this important process would be unwise.

For the Record

In November 2000, Luzenac discovered the "fatal flaw" in the NTP report. With the help of CRE we exploited this issue with NTP which ended in the deferral decision by the NTP Executive Committee.

The public record will reflect that Luzenac America was the only talc-interested-party who recognized this fatal flaw (and winning strategy).

Meli to NTP; Nov. 30, 2000

"A critical error in the fundamental logic of the NTP's own line of argument **categorically invalidates the NTP conclusion**....proposed by RG1 and RG2 that "Talc not containing asbestiform fibers is reasonably anticipated to be a human carcinogen."

"It is also recommended that the Board of Scientific Counselors Subcommittee notify Review Groups 1 & 2 that their conclusion relative to talc not containing asbestos fibers is not supported by the data. The arguments and assumptions made by the reviewers in the text of the Draft Background Document **unquestionably contradict their own conclusion**..."

"It is clear that the premise on which NTP has assessed the literature and safety issues relating to all forms of talc is **seriously faulted and cannot be used** as a reasonable basis for nomination as an anticipated human carcinogen."

Harris to NTP; May 1, 2001

"...and if they (RG1 and RG2 recommendations) were to be submitted to the Director of NTP and the Secretary as valid recommendations, a final decision to list talc not containing asbestiform fibers in the Report would be **arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law, and would be set aside by the Federal courts** pursuant to the Administrative Procedure Act."

.....

KEY POINTS

1. Joachim Roeser must understand that it was the strategy and actions of Luzenac America (not Luzenac Group or Eurotalc) that led to the talc deferral decision (in order for him to respect our current recommendations). Inexplicably, despite the soundness of our strategy, Luzenac Group repeatedly opposed our intended actions throughout the process.
2. CTFA and the talc interested parties have been minimally effective during this NTP review. It is a management problem. They have not demonstrated the leadership necessary to coordinate a diligent, on-going defense of talc. In the spirit of "Either lead, follow, or get out of the way", I recommend Luzenac America (with "CRE") advance our agenda with an invitation to others to follow. I do not favor the "committee approach" to NTP where no one is formally in charge.
3. I am not at all concerned about angering CTFA or any of its members who might be customers. With our entire business literally at stake, we have the "standing" to do what we feel is necessary in this battle for survival. As an aside, only J&J and possibly one other company expressed interest in further funding of the consultants utilized by CTFA last December.
4. We have every right to employ scientific reasoning and logic to the evaluation of health studies involving talc (outside of mineralogy issues). If we bring to light questionable conclusions or flaws in a published study, other experts can then be asked to forward their opinions on the issues. At a minimum, the NTP reviewers would be obligated to discuss and debate our points of contention (e.g., talc detected in ovarian tissue).

Exhibit 115

NARRATIVE
TALC – NTP REGULATORY CHALLENGE

Good morning everyone. My name is Steve Jarvis and I am responsible for Health, Safety, and Environmental matters for Luzenac America.

This morning...it is my distinct pleasure to present to you a summary of our most recent regulatory challenge involving the National Toxicology Program and their review of talc for potential listing in the 10th Report on Carcinogens.

But first....for those who may not know exactly what we doI'd like to introduce you to Luzenac America.

SLIDE 1

Luzenac America is part of the Luzenac Group of Companies. Headquartered in France, Luzenac Group is the world largest commercial producer of talc products.

In North America..... Luzenac America operates 4 talc mines and 8 talc milling operations.....We have large operations based in Ontario, Vermont, and Montana. Luzenac America is

1



headquartered in Denver Colorado where we also have our Research and Development Center.

Luzenac America mines and processes around a half-a-million tons per year generating approximately ^{Redacted} in sales.

Our major markets are talc sales to paper, polymers and paint markets..... and to a lesser degree, personal care products.....

You might be interested to know that we produce all the baby powder for Johnson & Johnson – including the talc for their popular adult product, Shower-to-Shower. As an interesting aside, would you believe that Luzenac talc also goes into Cipro?? It's True!.....

SLIDE 2

Our major regulatory challenge..... a challenge I might add that Luzenac absolutely could not afford to losecame from the NTP.

The NTP was authorized by the United States Congress to coordinate interagency toxicological testing and to publish the formal "Report on Carcinogens" which comes out about every 18-24 months..... To be listed in the RoC can be

devastating to a substance because of mandatory labeling requirements by OSHA and Proposition 65 in California.

In early 2000, NTP nominated talc for possible listing in the RoC because back in the early 1990's, the NTP published the results of a 2-year talc inhalation study on rats and mice and concluded that talc caused lung tumors in female rats.....

More on that in a minute.

SLIDE 3

A listing of talc in the RoC would have devastating consequences for the talc market worldwide.

First of all.....we would see a virtual immediate loss of our sales to the personal care market – around \$10 Million in sales in the first year.

Secondly.....because of the carcinogenic labeling requirements, we would likely suffer a deterioration of sales in all markets....perhaps anywhere from 20% to 50% of all remaining sales by year-three.

Additionally, a listing in the U.S. by NTP would likely trigger a carcinogenic status for talc in Europe and the Far East.

And finally..... because of our consumer product exposure, civil litigation would likely skyrocket.

As I mentioned, simply devastating consequences.

SLIDE 4

Now realistically..... there are some health issues with talc. For nearly 20 years, epidemiologists have been finding a weak, but persistent statistical link between the hygienic use of talc and ovarian cancer. However..... the studies are weakened by no one being able to offer any feasible “causal” explanations as to how and why talc would cause ovarian cancer.....but not a multitude of other cancers in the human anatomy.

As I mentioned, there is the 1992 rodent study by NTP, which found lung tumors in female rats. However, many other leading experts discount this finding claiming the tumors were a result of lung overload - simply too much inert dust in the lungs triggering an traumatic auto-immune response from the rats.

And finally, there is the long-held public perception that all talc contains asbestos. And even if it

doesn't, they are so similar chemically, that talc probably behaves like asbestos.

So these are some of the primary issues and concerns that served as the backdrop for the NTP review.

SLIDE 5

Okay....so here's what happened.

NTP announces in early 2000 that talc is going to be review. While this announcement catches us off guard, we are not alarmed.

But then, in October of 2000, NTP issues their draft report on talc and announces that the first two formal reviews resulted in votes to list talc as a carcinogen. The combined vote was 13-2 to list.

The entire talc industry, as well as companies like J&J were absolutely, positively, unquestionably, flabbergasted..... We simply could not believe it.

But now we had only two months to prepare for the third NTP review meeting..... a public meeting of the influential Board of Scientific Counselors Subcommittee. This occurred in December of last

year and we achieved a very dramatic turnaround. The BSC subcommittee voted 7-3 **not** to list talc.

And finally.....we fast-forward to this past June for the fourth and final review process. We see the NTP Executive Committee took the unprecedented action to actually “**stop**” the review process on talc and send it back to the beginning. They did this by deferring a final vote on talc.

And make no mistake about it, they knew if they proceeded with a listing nomination for talc, Luzenac America was going to challenge them in Federal Court.....and as the facts lay out, NTP would likely lose. Of that we are fairly certain!

SLIDE 6

Our successful defense strategy was threefold.

First.....we continued to work through the auspices of the CTFA – the Washington based trade association for the cosmetics industry. As you might imagine, Luzenac and Johnson & Johnson wield considerable influence on the talc subcommittee.

Secondly.....and this was our secret weapon, engage the services of the Washington based

Center for Regulatory Effectiveness, CRE. Since its formation in 1996 by several ex-high ranking officials in the OMB, CRE has grown into a nationally recognized...and relatively respected... regulatory watchdog organization. Federal agencies frequently come to them for assistance. CRE has also taken NTP to court.

And thirdly, we decided to be aggressive. This was a fight we simply could not lose. As such, we retained expert legal counsel to ensure we would have a solid foundation for a legal challenge if necessary.....it was the same firm which assisted CRE in their court battle with NTP.....and we also became very aggressive in our communication with NTP and other federal agencies. When didn't let the windows of "formal comment periods" become restrictive. We sent e-mails, faxes, overnight letters, and even telephones calls to key players in this battle....right up until hours before the final Executive Committee meeting.

And we believe these strategies paid-off.

SLIDE 7

While we certainly would have preferred a total victory – where NTP declared talc was not a human carcinogen.....we were relieved to at least get the review process “derailed” for now.....at least we have some “breathing space” to prepare a thorough, scientific defense of talc.

One of the issues we plan to focus on is demonstrating to NTP that virtually all of the epidemiology studies they previously used must be declared invalid for use in assessing talc “not containing asbestos”. This will be an expansion of the “Fatal Flaw” defense Luzenac employed in the first review on talc.

Additionally, we believe the latest epidemiology study which IS valid with regard to talc quality....it’s called the Gertig study.....and which also happens to be the largest study as well..... shows no increased risk of ovarian cancer. The significance of this study must be more heavily weighted than prior studies.

Any predictions at this point? Hard to say...but our hard fought victory this past year has given us some confidence and direction.

One last point.....lest we get complacent..
.....regardless of what happens with NTP, we
also have to keep an eye out for IARC. IARC
reviewed talc back in 1986 and concluded there
was insufficient evidence of talc carcinogenicity in
humans. We are hoping that this NTP activity
doesn't stimulate IARC conduct an "end-run"
around NTP declare talc a possible human
carcinogen.....because I think you all know,
we do not have the ability to become an active
participant in that relatively "closed" process.

Thank you for your time.

Exhibit 116

MAR. 26. 2002 7:38AM LUZENAC

NO. 610 P. 1



LUZENAC AMERICA

DENVER TECHNICAL CENTER
8985 E. NICHOLS AVE. • ENGLEWOOD, CO 80112 • USA

FACSIMILE

DATE: March 26, 2002	FROM: Richard J. Zazanski Director Product Safety
TO: Bill Ashton J&J	PHONE: 303-643-0404
	e-MAIL: rzazensk@luzenac.com
	FAX: 303-799-8926
cc:	Number of Pages: 13 pages (including Cover Sheet)

CONFIDENTIAL

Redacted



LUZENAC GROUP

Plaintiff's Exhibit
No.

P-27

exhibits@sticker.com

MAR.26.2002 7:38AM LUZENAC

NO.610 P.2

Redacted

One other note – We've been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen. But we must also keep an eye out for IARC. If they decide to re-review the status of talc because of all the ovarian epidemiology studies that have been published since 1986, IARC can surprise us all and decide to list "talc" as a potential human carcinogen. IARC reviews are not a public debate. Unlike NTP, IARC is answerable to no one politically (they are headquartered in Lyon, France of all places). As part of the World Health Organization, they act very independently to protect the citizens of this planet from "preventable" diseases. Their threshold for required medical evidence is predictably quite minimal.

You might want to counsel your management on this potential (and not to be too complacent about the status of talc).

Attached with this fax:

- 1 page on IARC (who they are).
- 2 pages on IARC's 1986 review of talc.
- 8 pages on their 1996 re-review of all forms of silica.

If any pages are unclear, please contact us.



**HP OfficeJet G Series G85
Personal Printer/Fax/Copier/Scanner**

**Fax-History Report for
TECHNICAL ASSURANCE
(908)874-1126
Mar 26 2002 8:16am**

Last Fax

<u>Date</u>	<u>Time</u>	<u>Type</u>	<u>Identification</u>	<u>Duration</u>	<u>Pages</u>	<u>Result</u>
Mar 26	8:15am	Sent	918593924202	1:06	1	OK

Result:

OK - black and white fax
Okay color - color fax

Exhibit 117



INTEROFFICE MEMORANDUM

DATE: September 12, 2000
TO: R. Bernstein; J. Gauntt; R. Meli
CC:
FROM: Carl E. Kollmar
SUBJECT: Cosmetics Consultant Update

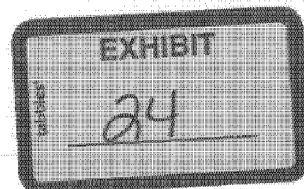
Richard Dodwell has filed his Progress Report. At this stage of the project he has completed all fax and telephone surveys and interviewed Luzenac's salespeople. At this time, there appears to be two problems with the market survey. First, several major body powder players have chosen not to respond to the surveys. This is an issue we need to consider. Second, Luzenac's major cosmetics distributor, WC&D, has not been interviewed. This is because Tom Grunstra, their in-house talc expert, has been out sick for several weeks.

Although we are missing input from several major players, I think there are some basic facts coming to light:

- Health is an issue to large body powder customers - a non-issue in other segments.
- The large volume body powder segment is not growing, although the decline of the past few years appears to have bottomed out. There is some growth in other segments.
- Other than soap bars, there appear to be limited growth opportunities (new markets/new products) for talc.

In my opinion, the large volume body powder portion of this business is not growing, it is price sensitive, there is aggressive competition (supplier and customer) and the oner of health concerns/liabilities hangs over it. This does not appear to be a market of opportunity for Luzenac at this time. Opportunities for growth appear to be limited to the soap bar segment - but the health/liability concerns remain.

In the details of Dodwell's report he identifies six major areas of interest: customer concerns, market growth, pricing, health concerns, competition and responsiveness to the survey.



Protected Document - Subject to Protective Order

LUZ006507

Customer Concerns

There are three major concerns expressed by customers:

- The closing of a Montana mine has caused some disruption in the market. I assume they are referring to the closing of the Beaverhead Mine and the subsequent discontinuance of the Supreme and Olympic products. Some customers are still using old stockpiled material and have either not found or tested a suitable alternate.
- The technical service from Luzenac has declined, but the rest of the service package (quality, delivery, etc.) is well regarded.
- The health issue is taken seriously by large users (mainly body powder customers), and mostly ignored by the smaller segments and packagers.

Market Growth

- The market is growing in many sectors, but remaining static in the body powder applications. It appears that business in the body powder segment is merely shifting around, particularly amongst the packagers.
- There are no new applications for talc, except some work in soap bars. One soap bar company, P&G, appears ready to move to customer trials and market testing.
- Surface treated talcs hold some promise, but more application research by the talc suppliers is needed to demonstrate the merits.

Pricing

- Pricing is an issue to the large volume consumers, but not an issue with the smaller higher value segments where quality, technical service and product performance are the key requirements expected of a supplier.

Health Concerns

- Some companies label their products "Talc Free", but this is more for advertising and sales promotion than to address health concerns.
- The general public is not aware of any health issues regarding talc.

Competition

- Most of the decline in talc usage has occurred during the past 5 years and has bottomed out.
- There are no serious replacement threats to talc. "Wheat", "Oat Flour" and "Corn Starch" are not direct threats to talc since they were introduced under the "natural" and "organic" banners. Although they have replaced some talc, they have proved to be less than ideal and are now more often used in blends with talc.

- Not many customers expressed a preference for a talc supplier, but those that did mentioned Luzenac.

Responsiveness to Survey

Several companies would not respond unless the survey sponsor was revealed – this was the over-riding concern of those that did not respond to the surveys. In addition, large body powder users were reluctant to respond to this survey because of health liability concerns and, to a lesser extent, because their companies have a policy against revealing confidential information.

At this point, Dodwell has contacted 96 companies and achieved a level of response slightly above 35% - I think this is better than expected.

- Twenty-one companies were called twice with no response and appear to use their voice mail as a screening tool. They include Coty, Kolmar Labs, Maybelline, Revlon (NJ), Colgate Palmolive and Amway.
- Eleven companies generally refused to participate in the survey. This group included J&J, MK Packaging, Thornton, Lancome/Cosmair, Lander, Estee Lauder and Revlon (NC).

Obviously, we are missing an input from several of the major players. To get their input we would have to either reveal the survey sponsor and/or raise their level of interest to respond. Their level of interest can be raised by appealing to their self-interest – "if I don't respond to this survey it may affect my supply of talc". In either case, a personal visit may be required. As I mentioned during my update at the last Management Meeting, revealing the sponsor or raising their level of interest is a double-edged sword – it either brings forth the desired response out of self-interest, or it generates a concern over the supplier's viability and loyalty to the market. It could cause them to consider other talcs or talc alternatives. At this point, I would recommend that Dodwell make no further extraordinary efforts to pursue those who are not responding. This can be a topic of discussion when Dodwell presents his findings at the October 5th meeting in Denver.

Exhibit 118



August 3, 1992

CONFIDENTIAL

SUBJECT: TALC FRANCHISE

TO: C. D. SIMONDS

Consumer confidence in talc has been slowly eroding, but among health care professionals, trust in its safety and benefits is poor. And, for the first time in over a decade, the FDA is now requiring reassurance. We have enjoined "risky" research with talc in the past - inhalation toxicity, translocation from the lungs, and genital migration studies. The time is ripe for some good news to definitively quieten theorizing critics.

My summary recommendations are as follows to re-establish our leadership in the talc category and rebuild its franchise:

1. Control any potential for inhalation by adding a small amount of lanolin oil to trap the respirables. This will also add a point of difference and improve both skin feel and benefits.
2. As rapidly as possible, complete the autopsy study of the mineral particle distribution in the organs of men versus women.

We should discuss this as soon as possible.

ADDENDUM

This morning I received your note attached to the new Cramer study. Our discussion earlier touched on this.

In summary:

- 1) A CTFA Task Force will fund a critical review of this paper, plus all other similar epidemiological studies to defuse the potential of anyone publishing a meta-analysis of all of them. You approved an expenditure for this effort.
- 2) The same CTFA Task Force will seek an evaluation of the NTP Inhalation Study which showed cancer in rodents. This refutation is critical to prevent the study results appearing on MSDS forms. You also approved our financial contribution to this effort.
- 3) At the first meeting of the Task Force, it was clear that "industry" agrees that a refutation of the ovarian cancer hypothesis based solely on discrediting existing publications, is only a "finger-in-the-dyke". I believe that they would be supportive of completing the autopsy study discussed above because it is the only way to finally put this issue to rest.

B. Semple

/cls

Johnson & Johnson

Office Of
GENERAL COUNSEL

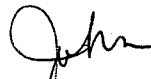
NEW BRUNSWICK, N.J.

December 5, 1994

SUBJECT: RITTER V. CYPRUS (WINDSOR MINERALS)

William Ashton ✓
Donald Jones

Redacted: Attorney-Client Privilege and Work Product



John C. O'Shaughnessy

JCO:jcm

Enc.

cc: R. Miller

Exhibit 119

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY

3
4 -----x

5 IN RE JOHNSON & JOHNSON) MDL No.
6 TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
7 MARKETING SALES PRACTICES,)
8 AND PRODUCTS LIABILITY)
9 LITIGATION)

10)

11 THIS DOCUMENT RELATES TO)

12 ALL CASES)

13 -----x

14

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT
15 PERSONAL CARE PRODUCTS COUNCIL,
by and through its Designated Representative,

16

MARK POLLAK

17

WASHINGTON, D.C.

18

WEDNESDAY, AUGUST 29, 2018

19

9:30 A.M.

20

21

22

23

24 Reported by: Leslie A. Todd

1 Deposition of MARK POLLAK, held at the offices
2 of:

3

4

5 SEYFARTH SHAW LLP

6 975 F Street, N.W.

7 Washington, DC 20004

8

9

10

11

12 Pursuant to notice, before Leslie Anne Todd, Court
13 Reporter and Notary Public in and for the District of
14 Columbia, who officiated in administering the oath to
15 the witness.

16

17

18

19

20

21

22

23

24

1 A P P E A R A N C E S

2

3 ON BEHALF OF THE PLAINTIFFS:

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5 GOLOMB & HONIK

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12 RYAN BEATTIE, ESQUIRE

13 BEASLEY ALLEN LAW FIRM

14 218 Commerce Street

15 Montgomery, Alabama 36103-4160

16 (800) 898-2034

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18 MICHELLE PARFITT, ESQUIRE

19 ASHCRAFT & GEREL, LLP

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21 Alexandria, Virginia 22311

22 (703) 997-1774

23

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16

17 ALSO PRESENT:

18 EMILY H. MANOSO, Staff Counsel, PCPC

19 THOMAS F. MYERS, Staff Counsel, PCPC

20

21 DANIEL HOLMSTOCK (Videographer)

22 JONATHAN VADERS (Technical Support)

23 ZACH HONE (Technical Support)

24

1	C O N T E N T S		
2	EXAMINATION OF MARK POLLAK		PAGE
3	By Mr. Golomb		8
4			
5			
6			
7	E X H I B I T S		
8	(Attached to transcript)		
9	POLLAK DEPOSITION EXHIBITS		PAGE
10	No. 1	The Plaintiffs' Steering Committee's	
11		Second Amended Notice of the	
12		30(b)(6) Deposition of Defendant	
13		Personal Care Products Council	30
14	No. 2	PCPC Organizational Chart	33
15	No. 3	Document with title "Talc IP -	
16		Revenue Received"	61
17	No. 4	Document entitled "Payments to	
18		Entities Identified in Plaintiffs'	
19		Notice of Deposition"	112
20	No. 5	CTFA Mission Statement, Bates	
21		PCPC0052417	127
22	No. 11	Bates IMERYS 118791	93
23	No. 12	Bates IMERYS 118792	132
24			

1 P R O C E E D I N G S

2 -----

3 THE VIDEOGRAPHER: We are now on the
4 record. My name is Daniel Holmstock. I am the
5 videographer for Golkow Litigation Services.
6 Today's date is August 29th, 2018, and the time is
7 9:30 a.m.

8 This video deposition is being held in
9 the law offices of Seyfarth Shaw, LLP, at 975
10 F Street, Northwest, in Washington, D.C., in the
11 matter of In Re: Johnson & Johnson Talc-Based
12 Powder Products Marketing, Sales Practices, and
13 Products Liability Litigation. It is pending
14 before the United States District Court for the
15 District of New Jersey, MDL No. 16-2738.

16 The deponent today is Mr. Mark Pollak.

17 Counsel will be noted on the
18 stenographic record. The court reporter is
19 Leslie A. Todd, who will now administer the oath.

20 MARK POLLAK,

21 and having been first duly sworn,

22 was examined and testified as follows:

23 EXAMINATION BY COUNSEL FOR PLAINTIFFS

24 BY MR. GOLOMB:

1 Q Good morning, Mr. Pollak. My name is
2 Richard Golomb. We met several years ago when I
3 took your deposition in -- in another one of these
4 cases.

5 Do you recall that?

6 A Yes, I recall.

7 Q And if you could keep your --

8 A Yeah.

9 Q -- voice up so everybody --

10 A Yes, I recall.

11 Q -- in the room can hear you.

12 And in preparation for your deposition
13 here today, did you have a chance to read your
14 deposition transcript from that prior deposition?

15 A Yes, I did.

16 Q All right. Let me just mention a couple
17 of things. As you -- I assume that you have seen
18 the notice of deposition which requires your
19 attendance here today.

20 A Yes.

21 Q All right. And we'll -- we'll go
22 through that in a little bit more detail.

23 As you may know, the -- this deposition,
24 unlike the prior deposition, is limited to some

1 topics that we have agreed to cover with you
2 while other topics will be covered with Dr. Loretz
3 and perhaps some other people from PCPC.

4 Do you understand?

5 A Yes.

6 Q All right. And your role in this
7 deposition is a little bit different than the
8 deposition previously. Do you understand that?

9 A Yes.

10 Q So that you understand that your
11 deposition -- and you certainly don't need to know
12 the rule, but it's under rule -- federal
13 Rule 30(b)(6). Have you heard that term before?

14 A I don't recall.

15 Q Okay. But you do understand that the --
16 the topics that are in the notice are the topics
17 that I'm going to be questioning you here today.

18 A Yes.

19 Q All right. And those topics have been
20 limited as a result of an order of the Special
21 Master who's been appointed in this case. Do you
22 understand that?

23 A Yes.

24 Q All right. And so you understand that

1 it may be later on in this litigation that you may
2 be required to give yet another deposition. I
3 know you're looking forward to that, but you may
4 have to.

5 Do you understand that?

6 A Okay. Yes.

7 Q All right. Let -- let me also ask you
8 about -- you signed a verification to some answers
9 to interrogatories recently. Do you recall that?

10 A Yes, on Monday.

11 Q All right. And let me just -- we're
12 going to go through some of these answers in a
13 little bit more detail later. But let me just
14 show you page 31. There's a verification dated
15 August 27, 2018, and it has your signature on it.

16 Is that your signature?

17 A Yes, it is.

18 Q And did you in fact sign that on
19 August 27th?

20 A Yes, I did.

21 Q And when did you first see the
22 questions, the interrogatories?

23 A I may have just seen them on that
24 Monday. Some of them I may have seen previously,

1 but I can't -- I can't be sure.

2 MR. GOLOMB: Okay. I just want to just
3 say for the record that we received the answers to
4 these interrogatories -- interrogatories on
5 August 27th, 2018, at 4:45 p.m. There was an
6 agreement of counsel that these would be supplied
7 a week in advance of this deposition. Obviously
8 they weren't. So we -- we may -- after we look at
9 the interrogatory answers in more detail and
10 compare them to some records, we may be required
11 to come back and take another day of deposition on
12 this 30(b)(6) notice.

13 You don't need to respond to that. I
14 just wanted to let you know that that's -- that's
15 a possibility.

16 BY MR. GOLOMB:

17 Q When did you first find out that you
18 were going to be deposed?

19 A In this particular case?

20 Q Yeah.

21 A I would -- a few months ago, I would
22 think.

23 Q And have you been deposed in any other
24 cases other than the deposition I took of yours --

1 A No.

2 Q -- several years ago?

3 A No.

4 Q All right. And how did you learn that
5 you were going to be deposed?

6 A I think Tom Myers, our in-house counsel,
7 shared with me the fact and may have -- may have
8 forwarded the notice. I don't recall.

9 Q Okay. And since you learned that you
10 were going to be deposed again, I -- I assume that
11 you met with Mr. Myers in-house?

12 A Right. As well as Tom Locke.

13 Q Okay. Did you have any meetings with
14 Mr. Myers alone?

15 A I don't think so.

16 Q Did you speak to any other employees of
17 PCPC from the time that you -- you received notice
18 that you were going to be deposed until today?

19 A Not regarding the substance of the
20 deposition.

21 Q Were you aware that Linda Loretz was
22 deposed?

23 A Yes, I was.

24 Q How did you become aware that Linda

1 Loretz was deposed?

2 A Because I think I was copied on the
3 e-mail stream of trying to find mutually agreeable
4 dates for both of our depositions.

5 Q Okay. And before Ms. Loretz was
6 deposed, did you have any conversation with her
7 about her upcoming deposition?

8 A No, I did not.

9 Q And since she's been deposed, did you
10 have any conversation with her about her
11 deposition?

12 A No, I have not.

13 Q So you've never discussed with Linda
14 Loretz the content of either yours or her
15 depositions?

16 A Correct.

17 Q Did you read your deposition transcript?

18 A Yes, I did.

19 Q Did you read Linda Loretz's deposition
20 transcript?

21 A No.

22 Q So you didn't read the deposition
23 transcript that I -- of the deposition that I took
24 of Linda Loretz several years ago?

1 A That I can't recall.

2 Q You may have?

3 A But not -- but not in context of
4 preparing for this.

5 Q Okay. What -- if not for preparing for
6 this, why else would you read Linda --

7 A I don't --

8 Q Let me --

9 A I don't recall reading it.

10 Q Let me just give you one instruction.

11 You're doing fine, but if you will allow
12 me to finish my question, I will allow you to
13 finish your answer. That way --

14 A Sure.

15 Q -- neither one of us gets in trouble
16 with the court reporter. Okay? Okay?

17 A Yes.

18 Q And you also have to give a verbal
19 response.

20 A Yes.

21 Q All right. In what other context would
22 you read the deposition if not -- if not to either
23 prepare for this deposition or to have a
24 conversation with somebody?

1 A I can't think of any other context. I
2 know in preparation for this, I did -- I had read
3 the transcript of my original deposition whenever
4 the transcript became available last time, and I
5 think I -- I noted there were a few errors in the
6 transcription, and I did review that. And so in
7 preparation for today, I did read over that
8 deposition last week.

9 I did not read Linda's and I have no
10 recollection that I have, but I don't want to say
11 definitely that I didn't. It was
12 two-and-a-half -- more than two-and-a-half years
13 ago.

14 Q And when you say there were errors in
15 the transcription, what do you mean?

16 A There were -- they ask you to fill out a
17 form on different words the transcriber got wrong.

18 Q Okay.

19 A And that was filed with the deposition.

20 Q Was there any -- any errors in the
21 substance of what you said?

22 A I would say most of it was minor.

23 Q And is there anything that you read in
24 that deposition that you would now -- when you

1 read it you said, That wasn't right, or, Boy, I
2 wish I hadn't said that?

3 A No.

4 Q Anything like that?

5 A Nothing.

6 Q So whatever you said to -- whatever your
7 answer was to whatever my question was at that
8 earlier deposition, you stand by those answers?

9 A Yes.

10 Q When -- when did you learn that you were
11 going to be deposed?

12 A In this particular instance?

13 Q Yeah.

14 A I think in June or July.

15 Q And the meeting that you had -- well,
16 strike that.

17 You said you found out from Tom Myers.
18 Was that in person?

19 A It probably was on -- being copied on an
20 e-mail string.

21 Q And did you have a conversation with Tom
22 Myers?

23 A I -- I possibly did about this. I -- I
24 don't recall. I talk to him about lots of things,

1 so --

2 Q Okay. Well, have you ever had --
3 since -- since you received notice in June or July
4 of 2018 that you were going to be deposed here
5 today, have you ever had a one-on-one conversation
6 with Tom Myers about the fact that you were being
7 deposed here today?

8 A I probably did in terms of the
9 logistics.

10 Q Okay. Did you have any conversation
11 with Tom Myers about the substance?

12 A I don't think I did. Any conversation
13 would have been in the presence of Tom Locke.

14 Q And did you have any conversation
15 again -- I'm only restricting my questions to any
16 one-on-one meetings that you may have had with Tom
17 Myers.

18 Did you have any meeting, telephone
19 call, e-mail exchanges with Tom Myers about the --
20 about either, A, the substance of your deposition
21 here today or, B, how to prepare for the
22 deposition?

23 A Well, I think we did have a conversation
24 about how to prepare because we agreed that we

1 would meet with Tom Locke to review it.

2 Q Okay. And when was the first
3 communication that you had with Tom Locke after
4 you learned that you were going to be deposed here
5 today?

6 A Well, I met with him for the first time
7 in preparation for this last week.

8 Q Okay. So you had no conversation with
9 Tom Locke in June?

10 A I don't think so. I think it was all
11 through e-mails trying to find mutually agreeable
12 dates.

13 Q And the -- you had no communications
14 with Tom Locke other than the logistics of the
15 deposition in July?

16 A That's -- that's my recollection.

17 Q And -- and your testimony here today is
18 that the first time that you met with Tom Locke to
19 discuss your preparation for this deposition was
20 last week?

21 A That's correct.

22 Q Okay. And when last week was that?

23 A I'm not even sure which day. Possibly
24 Tuesday or Wednesday. I don't recall.

1 Q So either August 22nd or August --
2 either August 21st or 22nd?

3 A I think so, yeah.

4 Q And is that the first communication of
5 any kind you had with Tom Locke other than
6 logistics of when to meet since you received
7 notice of the -- received notice that you would be
8 deposed?

9 A I'm fairly certain.

10 Q And how long did your meeting last on
11 Monday or Tuesday of last week?

12 A I think it was three hours or less.

13 Q Okay. And without telling me about any
14 conversation that you may have had with Mr. Locke,
15 because that's a privileged communication, tell me
16 what you did during that three hours.

17 A We reviewed some potential questions and
18 some of the topics, what -- some of it was really
19 to refresh my memory on the whole process and what
20 to expect today and what I was expected to cover.

21 Q And was -- and is -- at that time did
22 you also review the deposition notice with -- that
23 included the topics?

24 A I actually don't recall.

1 Q Did you review any documents during that
2 three-hour period?

3 A I don't think so.

4 Q Did you review any documents to prepare
5 yourself before you had that meeting last week
6 with Tom Locke?

7 A I reviewed a few things in the office to
8 refresh my memory because there were topics that
9 were discussed in the last deposition, and I
10 wanted to be fresher on them.

11 Q Okay. What did -- what did you review?

12 A For example, the Cosmetic Ingredient
13 Review procedures that are online.

14 Q And specifically what is it that you
15 wanted to refresh your memory about as it relates
16 to the CIR?

17 A So there were some topics in the -- in
18 the last deposition that involved CIR, and I
19 wanted to be -- and I knew also some of the
20 procedures had changed in the last year, and I
21 wanted to be fresher on them.

22 Q What procedures changed in the last
23 year?

24 A There were a few updates and elimination

1 of redundancies, a couple of things that they
2 hadn't done in 20 or more years that they felt
3 were no longer...

4 Q Give me an example of what you're
5 talking about.

6 A I -- I can't even tell you off the top
7 of my head. They were really all pretty minor.

8 Q Okay.

9 A The CIR steering committee met in early
10 June to review the proposed changes to the
11 procedures and approve them then, and then they
12 were updated on our website.

13 Q And in June of 2018?

14 A Correct.

15 Q Okay. And do you know why those --
16 those procedures were changed?

17 A Because they -- a few of the things were
18 no longer necessary or practical and were
19 outdated. I think the procedures hadn't been
20 changed in ten or more years.

21 Q And were -- were those changes made at
22 all because of the talc litigation?

23 A Nothing related to talc.

24 Q Okay. So before you met with Tom Locke

1 last Monday or Tuesday, what other documents did
2 you review to help prepare yourself?

3 A He shared --

4 Q No, before you met.

5 A I don't think I reviewed anything before
6 I met with him.

7 Q Other than the CIR review?

8 A Right, and that was subsequent to our
9 meeting.

10 Q Okay. So then let's just be clear, then
11 you find out about the -- the deposition in June
12 or July. You have some conversation about
13 logistics with Mr. Myers. Don't have any
14 conversations with Tom Locke. You may have had an
15 exchange of e-mails to discuss logistics. You
16 finally agreed on a date to meet, which was early
17 to mid last week, and up until that time of that
18 meeting, you didn't review anything to assist you
19 in the preparation for today's deposition.

20 A Correct.

21 Q And then you -- you go to meet with
22 Mr. Locke, and you review some questions and some
23 potential answers to your deposition, but again,
24 on that particular day in the three-hour meeting,

1 you don't review any documents. Is that your
2 testimony?

3 A Yes.

4 Q Okay. And so who else was in the room
5 when you met for three hours with Mr. Locke?

6 A Tom Myers and Emily Manoso, who's our --
7 who also is a lawyer for the council.

8 Q Okay. And is that somebody who works --

9 A Right, she --

10 Q -- with Mr. Myers?

11 A Yes. She's in the room today.

12 Q Okay. Anybody else in the room?

13 A No.

14 Q Anybody from Mr. Locke's office in the
15 room?

16 A No.

17 Q And in -- at what time of day did this
18 meeting take place?

19 A In the morning.

20 Q And what time did it end?

21 A By 12:30.

22 Q And did you have any -- after you met
23 with Mr. Locke that day, did you discuss what
24 happened at that meeting with -- with Mr. Myers?

1 A No, I don't think I did.

2 Q Did you have any -- any homework
3 assignment, if you will, on what you should do
4 next to help yourself prepare for the deposition?

5 A No, and I don't remember the sequence of
6 events, whether I reviewed the transcript before
7 or after that meeting.

8 Q Okay. But you reviewed the transcript
9 of the prior deposition.

10 A Correct.

11 Q But you did not review the deposition of
12 Linda Loretz.

13 A Not -- not recently. I -- again, I'm
14 not sure whether I did two or more years ago.

15 Q Okay. And when you -- when you left
16 Mr. Locke after that three-hour meeting, had you
17 scheduled your next meeting?

18 A No, we hadn't.

19 Q Did you have a next meeting?

20 A Yes.

21 Q When was the next meeting?

22 A Yesterday.

23 Q Okay. And so -- and what time was that
24 meeting yesterday?

1 A It was also in the morning.

2 Q And how long did that meeting last?

3 A Two, two-and-a-half hours maximum.

4 Q Okay. And other than the possibility
5 that you may have read your -- your deposition
6 transcript from the prior deposition in that week
7 or so intervening period of time, did you review
8 any other documents?

9 A So we went over the document that --

10 Q Let me -- I'm sorry. Let me be clear
11 about my question.

12 You had told us that you read the --
13 your deposition transcript from the prior
14 deposition, but you weren't sure if it was before
15 or after that first meeting with Mr. Locke,
16 correct?

17 A Yes.

18 Q All right. And -- and so when you left
19 that meeting, you then scheduled another meeting
20 with Mr. Locke a week or so later, which would
21 have been two days ago, correct?

22 A We actually left it open whether we were
23 going to meet, but we decided we would.

24 Q Okay. But ultimately you decided to

1 meet on Monday.

2 A No. Yesterday was Tuesday.

3 Q Yesterday. And that was the first -- is
4 that the first conversation you had with Mr. Locke
5 since you left his office back on the 21st or
6 22nd?

7 A Yes.

8 Q And so my -- my -- going back to my
9 earlier question, from the time that you left
10 Mr. Locke's office on the 21st or 22nd until the
11 time you saw him yesterday, did you -- other than
12 the possibility that you may have read that prior
13 transcript, did you read any -- any -- did you
14 look at any documents?

15 A Well, again, because I signed the
16 interrogatories on Monday, I did read them.

17 Q Okay. I'm talking about before you met
18 with Mr. Locke on Monday.

19 A Well, I -- I reviewed the document and
20 signed it on Monday. I met with Mr. Locke on
21 Tuesday.

22 Q Okay. My question is, from the time
23 that you left Mr. Locke's office last week until
24 the time that you saw Mr. Locke this week, okay,

1 did you review any other documents?

2 A Not besides the interrogatories.

3 Q Okay. How did you receive the answers
4 to the -- the answers to interrogatories?

5 A Electronically, and then we printed them
6 out.

7 Q Okay. And when did you get those?

8 A On Monday.

9 Q And -- and you were in your office when
10 you received them?

11 A Yes.

12 Q And you reviewed them in your office?

13 A Yes.

14 Q And were the -- did you have any
15 conversation with Mr. Locke about those answers
16 before you received them electronically on Monday?

17 A No.

18 Q Okay. So just to be clear, that your --
19 in your office on Monday, at that point you had
20 never seen the -- the set of interrogatories. Am
21 I correct?

22 A This particular set, yes.

23 Q Right. And then you -- you get a set of
24 interrogatories that are both questions and

1 answers. The answers are already provided for
2 you. You're sitting in your office, you get them
3 electronically, you review them, and you sign the
4 verification.

5 A Yes.

6 Q And did you make any changes to the
7 answers?

8 A No.

9 Q Did you have any conversation with --
10 with Mr. Locke about those answers before you
11 signed the verification?

12 A No.

13 Q Did you have any conversation with
14 Mr. Myers before you signed the verification?

15 A I think I may have said to him, These
16 look fine.

17 Q Okay. So it's fair to say you didn't
18 have any input into the answers?

19 MR. LOCKE: Objection.

20 THE WITNESS: I -- these interrogatories
21 were similar in substance to many interrogatories
22 I've signed or reviewed in the past few years.

23 BY MR. GOLOMB:

24 Q Okay. In this set you didn't have any

1 input into the answers. Am I correct?

2 MR. LOCKE: Objection.

3 THE WITNESS: Correct.

4 BY MR. GOLOMB:

5 Q Okay. So the -- the -- did you only
6 have one meeting with Mr. Locke before -- this
7 week before today?

8 A I had one meeting last week, one meeting
9 yesterday.

10 Q I understand. So -- so this week
11 your -- other than today, this week your sole
12 meeting was yesterday?

13 A Yes.

14 Q All right. And when did that meeting
15 start, what time of day?

16 A 9:30.

17 Q And when did that meeting end?

18 A It ended I think by 12 o'clock.

19 Q Okay. And did you review any other
20 documents during that three-hour period of time?

21 A He may --

22 MR. LOCKE: It's just a "yes" or "no."

23 THE WITNESS: Yes.

24 BY MR. GOLOMB:

1 Q What did you review?

2 MR. LOCKE: Well, I'm not going to --
3 our selection of documents that I might have
4 showed the witness, that reflects our work
5 product. So he's not going to answer that
6 question. If you show him a document, you can ask
7 him if he reviewed it.

8 BY MR. GOLOMB:

9 Q Approximately how many documents did you
10 review?

11 A Two or three.

12 Q Well, let's -- let's go to the -- to the
13 notice for a second.

14 Mr. Pollak, for the record, we're going
15 to mark this as Pollak No. 1, and you can see
16 there's a red flag, and we will go right for
17 page 12, where the red flag is.

18 (Pollak Exhibit No. 1 was marked
19 for identification.)

20 BY MR. GOLOMB:

21 Q And you can see what I've done is I've
22 highlighted specifically the -- the topics that
23 you're noticed here today to answer. Okay?

24 A Yes.

1 Q And so let's start with under
2 subsection 3, "Issues relating to influence and
3 bias." Do you see that?

4 A Yes.

5 Q And under 3.1, PCPC, so you are here
6 today to answer my questions concerning the
7 purpose, function, responsibilities and missions
8 of PCPC. And you're also here to talk about
9 PCPC's structure, membership, dues system,
10 assessments, budgeting committees, and funding,
11 including entities funded in whole or in part by
12 PCPC, and financial contributions made to PCPC.

13 Do you feel you're prepared to answer
14 those questions today?

15 A Yes.

16 Q If we go to the next page, page 13 of
17 that document, under number 2: You are also here
18 to answer questions about PCPC's relationship with
19 J&J and J&JCI, including formal and informal J&J
20 and J&JCI representatives and J&JCI or J&J
21 financial contributions to PCPC, including to
22 committees and/or subcommittees.

23 You feel you're prepared to answer
24 questions about that today?

1 A Yes.

2 Q Under subsection 3, under Imerys, you're
3 here to answer questions about PCPC's relationship
4 with Imerys, including formal and informal
5 representatives, and financial contributions to
6 the PCPC, including to committees and/or
7 subcommittees.

8 Do you feel like you're prepared to
9 answer questions about that today?

10 A Yes.

11 Q If you go to page 15 of the document.
12 It's entitled "National Cancer
13 Institute" under subsection 7. Do you see that?

14 A Yes.

15 Q Under subsection (b), you're here to
16 talk about the knowledge concerning financial
17 support to NCI and the persons who make
18 recommendations to NCI within the -- within and
19 outside the organization.

20 Do you feel like you're prepared to
21 answer those questions?

22 A Yes.

23 Q And under subsection 10, on page 16 --
24 you'll see on page 15 it says "The cosmetic

1 industry review," and subsection (d) is: "PCPC's
2 relationship with CIR, including funding,
3 staffing, membership, formal and informal
4 meetings, committees and/or subcommittees."

5 Do you feel like you're prepared to
6 answer questions on those topics today?

7 A Yes.

8 Q Okay.

9 MR. GOLOMB: Let's mark this as No. 2.
10 There's some extra copies there. This will be
11 marked as Plaintiffs' Exhibit 2.

12 (Pollak Exhibit No. 2 was marked
13 for identification.)

14 BY MR. GOLOMB:

15 Q While Mr. Locke is circulating that,
16 Mr. Pollak, you understand, do you not, that your
17 answers here today as a 30(b)(6) deponent are
18 binding on PCPC?

19 A Yes.

20 Q So you're not just here in your own
21 personal capacity. You understand that, correct?

22 A I'm a corporate representative.

23 MR. GOLOMB: Now, I'm going to show him
24 the document.

1 MR. LOCKE: Oh, okay. Do you want to
2 mark this?

3 MR. GOLOMB: Yeah, this one is marked.
4 Why don't you give me that one back. Thanks.

5 BY MR. GOLOMB:

6 Q Now, you're familiar with this document,
7 are you not?

8 A Yes.

9 Q This is an organizational chart. In
10 fact, it's an organizational chart that you
11 supplied to me right before the last deposition.
12 Do you recall that?

13 A Yes.

14 Q Is this an organizational chart that
15 you -- that you yourself prepared, or is this
16 something that was previously prepared that you
17 brought with you at that prior deposition?

18 A I actually don't recall.

19 Q Okay. Is this something -- whether or
20 not it was specifically for that deposition or
21 not, is this something that you prepared?

22 A I would have reviewed it. I don't
23 recall that I would have prepared it at the time.

24 Q Okay. What -- what's your title?

1 A So I'm on this as senior executive
2 vice president. At the time it was strategic
3 initiatives membership and marketing. It's now
4 changed to senior executive vice president, chief
5 operating officer.

6 Q Okay. And this was previously marked on
7 February 18, 2016, the date of our prior
8 deposition, correct?

9 A Well, here it's marked today's date. So
10 I -- I wouldn't know.

11 Q Okay. Well, let me show you the prior
12 copy where -- you see?

13 A Okay. Yes.

14 Q Is that consistent with your
15 recollection of when the prior deposition was?

16 A Yes.

17 Q And you've got a change of title since
18 then. Do you have -- is your job description
19 different?

20 A It's fairly similar.

21 Q How would you -- what's your job
22 description?

23 A I am the -- the chief operating officer
24 responsible for working with all the senior staff

1 on providing -- in coordinating our policies and
2 our approach so we can best represent the industry
3 and be responsive to our board of directors.

4 Q And is it -- you're not a scientist,
5 correct?

6 A Correct.

7 Q And is it fair to say that your -- your
8 job is more kind of internal administrative than,
9 you know, scientific or public relations or
10 political?

11 A Yes, but it involves all those
12 components because I have to work with all the
13 EVPs on -- on the major issues.

14 Q And let's just go through this, if we
15 could, because I think what this does is it gives
16 us the -- kind of the different departments within
17 the organization, correct?

18 A Yes.

19 Q How many current employees are there at
20 PCPC?

21 A I think the count is around 56.

22 Q All right. And first of all, looking at
23 page 1 of Exhibit 2, is Lezlee Westine -- is it
24 Westin (phonetic)?

1 A Westine.

2 Q Westine. Is she still the president and
3 CEO?

4 A Yes, she is.

5 Q And just as we quickly go through the
6 employees on the bottom of the page, are they all
7 the same or have there been changes?

8 A So there are two changes. The first one
9 is Elizabeth Anderson is no longer there. Tom
10 Myers is EVP, legal and general counsel.

11 Q What's the other change?

12 A And the other one is the EVP Science,
13 Beth Lange, is no longer there and her replacement
14 is Alexandra Kowcz.

15 Q Alexandra?

16 A Right.

17 Q Couch?

18 A K-O-W-C-Z.

19 Q And why did Elizabeth Anderson leave?

20 A She retired.

21 Q And why did Beth Lange leave?

22 A She relocated with her husband to Utah.

23 Q If we go to the next page of the
24 exhibit. Looking at the legal department, any

1 changes?

2 A Right. So Farah Ahmed has also left,
3 and Emily Manoso has taken her slot.

4 Q And why did Farah Ahmed leave?

5 A She left for another job.

6 Q And do you know where that is?

7 A Yes. The organization changed to -- its
8 name is Fragrance Creators. It's a trade
9 association representing fragrance ingredient
10 manufacturers.

11 Q The next department is Government
12 Affairs department. First of all, tell me
13 generally what Government Affairs department does.

14 A So that would be the closest to lobbying
15 federal and state relations, representing the
16 industry before different state regulatory bodies
17 and federal.

18 Q Okay. Any -- any changes in that
19 department since the last deposition?

20 A No.

21 Q On the next page, Public Affairs and
22 Communications.

23 A So there -- Lisa Powers is still there.
24 The other two people have left. Jewel Jones has

1 taken Hayley McConnell's position, and Jamie Kirk
2 has taken Lauren Brady's position.

3 Q What does Public Affairs and
4 Communications department do?

5 A So they work with our members to present
6 the industry's viewpoint to the media, monitor how
7 the industry is being covered by the media, and
8 work on external communications materials for the
9 organization.

10 Q And when you say "external materials,"
11 what do you mean?

12 A For example, our annual report. We're
13 in the process of redoing our website, and they're
14 working on the website redesign.

15 Q And why did Hayley McConnell leave?

16 A I think she decided to stay home with
17 her children.

18 Q And why did Lauren Brady leave?

19 A I think she got a better job.

20 Q Where is she?

21 A I don't recall.

22 Q What does Global Strategies department
23 do?

24 A So that's our international department.

1 We monitor and advise our members on a lot of
2 international cosmetic regulations, and they're
3 the department that handles that. It also works
4 to get uniform regulation worldwide of cosmetics
5 and represent the industry's viewpoint on trade
6 negotiations.

7 Q And when you say "works to get uniform
8 regulation worldwide of cosmetics," what do you
9 mean?

10 A So that the -- for example, the
11 regulations in the European Union would be
12 compatible with FDA regulation so that companies
13 who sell their products in numerous markets do not
14 have to comply with inconsistent regulations.

15 Q And have any of the employees within the
16 Global Strategies department changed?

17 A Yes. Tonya Kemp is no longer there, and
18 Natalie Obermann, I think is her last name, has
19 replaced her.

20 Q Why did Tonya Kemp leave?

21 A She left for a better job.

22 Q Where did she go?

23 A She's working for Amway.

24 Q And Finance and Administration, what --

1 what do they do?

2 A So that is the accounting, human
3 resources, information technology, things like
4 that.

5 Q Is that where -- did you come up -- in
6 the company come up through finance and
7 administration?

8 A Not really. It was a separate
9 department from that.

10 Q What department did you come up through?

11 A It's no longer a separate department.
12 At the time it was member relations.

13 Q Okay. Any changes in Finance and
14 Administration?

15 A Yes. So we no longer have a
16 vice president of finance, and -- he retired. And
17 we have -- the person who took his place, Al Fox,
18 I actually don't know -- don't recall his new
19 title, but he is higher than an accounting manager
20 but he's not a vice president.

21 Q Okay. Any other changes for Finance and
22 Administration?

23 A So we no longer have a receptionist who
24 is an employee of the council. We have somebody

1 from a temp agency. And there are -- there's a
2 new staff accountant.

3 Q Who is that?

4 A Dan, and I can't remember his last name.

5 Q Now, on this -- on this document it says
6 "Accounting manager, vacant," and you described Al
7 Fox as the accounting manager. Is that --

8 A No, he's higher than an accounting
9 manager. So what would be here, the VP finance
10 accounting manager and staff accountant, we
11 currently are handling with two full-time
12 employees, and then it's supplemented by a --
13 either a part-time or a temporary accounting
14 employee, who is just there two or two-and-a-half
15 days a week.

16 Q And then on -- you also have the Science
17 department. What does the Science department do?

18 A So the Science department works with our
19 member companies on -- to monitor the -- the
20 latest information on science data, ingredient
21 safety relating to our products. There are a
22 number of committees. We have international
23 nomenclature that's handled through a committee in
24 the Science department that forms the platform for

1 the database services that we have for our
2 members, and we do a variety of science and
3 technical publications that are based on this
4 nomenclature and other...

5 Q Give me an example of a standing
6 committee.

7 A So the pharmacology and toxicology
8 committee.

9 Q Now, there are a number of interested
10 party task forces, correct?

11 A Yes.

12 Q And as an example, we know that there is
13 a Talc Interested Party Task Force, correct?

14 A Yes.

15 Q And is -- first of all, is the Talc
16 Interested Party Task Force considered a standing
17 committee?

18 A No.

19 Q What's -- what is it considered?

20 A It's a -- it's a task force, so a task
21 force would be of limited interest to the broad
22 membership.

23 Q Okay.

24 A A standing committee would be a concern

1 or a topic that's much more common among them.

2 Q And do task forces kind of come and go
3 depending on the issue of the day as it relates to
4 that particular task force?

5 A Some of them do. Some of them are
6 around for a long time.

7 Q Okay. How would you describe -- in that
8 context, how would you describe the Talc
9 Interested Party Task Force?

10 A It's obviously been in existence for
11 quite a while.

12 Q And when was it started?

13 MR. LOCKE: Well, objection. It's
14 beyond the scope.

15 You can answer if you can.

16 THE WITNESS: I don't recall. I think
17 probably in the 1980s.

18 BY MR. GOLOMB:

19 Q And why was it started?

20 MR. LOCKE: Objection. Beyond the
21 scope.

22 THE WITNESS: I don't know. I mean,
23 I -- I think it started before I came there.

24 BY MR. GOLOMB:

1 Q When -- when did you come to the
2 company?

3 A In 1983.

4 Q Okay. And so the Talc Interested Party
5 Task Force was started obviously before 1983.

6 A I think so.

7 Q Okay. Are you aware one way or the
8 other as to whether or not the Talc Interested
9 Party Task Force was started in response to Dr.
10 Dan Cramer's study back in 1982?

11 MR. LOCKE: Objection. Beyond the
12 scope.

13 THE WITNESS: I don't know who Dr. Dan
14 Cramer is.

15 BY MR. GOLOMB:

16 Q Okay. So in terms of the standing
17 committees, approximately how many of them are
18 there?

19 A Maybe 25. I think we provided a -- the
20 committee roster and description.

21 Q And in terms of the interested party
22 task forces, approximately how many of them are
23 there?

24 A There could be 10 to 20. Some of them

1 are not particularly active. They're more contact
2 lists.

3 Q Give me an example of a -- of the
4 currently active task force other than talc.

5 A Sunscreen.

6 Q All right. Looking at the Science
7 committee on this document, any changes?

8 A We already noted Beth Lange. John
9 Krowka has retired. And Carmela Wingfield has
10 left.

11 Q Did somebody take Beth Lange's place?

12 A Right. Alex Kowcz. Couch (phonetic).
13 I always get this messed up.

14 Q Did somebody take John Krowka's place?

15 A Yes. Dan, and I don't remember his last
16 name.

17 Q Anybody take Carmela Wingfield's place?

18 A No.

19 Q If we go to the next page, Strategic
20 Initiatives, what is that?

21 A So that was from my old title, and then
22 they had Marketing and Member Services as a
23 separate department.

24 Q What is Strategic Initiatives?

1 A So, again, it was, you know, working on
2 the major program initiatives for the association
3 and working with the board of directors to
4 implement policies and --

5 Q When you say "program initiatives," what
6 do you mean?

7 A You know, different -- whether it's in
8 the sustainability area or animal testing,
9 alternatives, things like that.

10 Q Marketing and Member Services, any
11 changes?

12 A So Jennifer Harwell has left for another
13 job. Catherine McDonald was promoted and is
14 handling membership as well as meetings. Huyen
15 Tran has retired. And Ashley Hilton has left, and
16 Carmela Douglas, who was the former receptionist,
17 has taken over her slot.

18 Q So Carmela --

19 A -- Douglas, who is on the organ- -- this
20 organization chart as the receptionist.

21 Q So are you --

22 A Carmen.

23 Q On this chart that you've provided to us
24 in February of 2016, it identifies you as the

1 senior EVP membership and marketing.

2 Do you still maintain that title?

3 A No. It has -- it has both titles, and
4 I -- I don't know why.

5 Q Do you still maintain that job function?

6 A They were -- I sort of absorbed that job
7 function into my current job.

8 Q Okay. And did anybody take over
9 Catherine McDonald's position?

10 A No, she's still there. She got promoted
11 and has taken over Jennifer Harwell's position.

12 Q Okay. Anybody take over Jennifer
13 Harwell's position?

14 A No. That's vacant.

15 Q Anybody take over as operations manager?

16 A We have a part-time employee who is
17 handling what Mr. Huyen did.

18 Q And what's that person's name?

19 A Mr. Xu.

20 Q Okay. If we look at the next page, it's
21 got the organizational chart for the Personal Care
22 Products Council Foundation. What is that?

23 A So it is a separate entity that runs our
24 Look Good Feel Better program for women undergoing

1 cancer treatment.

2 Q And what is the Look Good Feel Better
3 program?

4 A We provide makeover sessions for women
5 undergoing cancer treatment to help them deal with
6 the side effects of chemotherapy and radiation.

7 Q And what is the approximate revenue base
8 for that?

9 A So that is entirely based on
10 contributions and proceeds from fundraising
11 activities and cause marketing programs.

12 Q And approximately how much revenue per
13 year is in that program?

14 A I think it's close to \$2 million.

15 Q Where does the money come from?

16 A I just said contributions, cause
17 marketing agreements.

18 Q Contributions from -- from who?

19 A From women who've undergone the program,
20 other people in the cancer community, but it's
21 more the proceeds from fundraising events and
22 cause marketing programs.

23 Q And these seven people who are
24 identified as employees of the Personal Care

1 Products Council Foundation, are they also
2 considered employees of the Personal Care Products
3 Council?

4 A Yes. So they're part of our personnel
5 system and salary and benefits, but the -- the
6 money to pay them and their benefits and a
7 percentage of the overhead comes from the
8 foundation.

9 Q And these seven people, have that --
10 have there been any changes since?

11 A Yes. This Alexandra is no longer there,
12 and she's been replaced by Shayma, and I can't
13 remember her last name.

14 Q Okay. In addition to the individual
15 contributions that you were just talking about, do
16 you get any contributions into the foundation from
17 any of the PCPC members?

18 A So the -- the member companies, yes, do
19 provide a lot of the funding indirectly because of
20 this major fundraising event called the DreamBall
21 that's held in September in New York. Until this
22 year, we had done it in partnership with the
23 American Cancer Society. So the companies buy
24 tables, and most of these -- many of them are

1 member companies, and then there are other
2 fundraising activities associated with the event.

3 Q Okay. Is it fair to say that the --
4 that the DreamBall fundraiser is your number one
5 fundraiser for the foundation?

6 A Yes.

7 Q And does -- is J&J -- J&J, are they a
8 sponsor of the DreamBall?

9 A They're certainly a participant, yes.

10 Q And do you know -- can you tell me
11 approximately how much on an annual basis they
12 contribute to the foundation?

13 A I can't tell you exactly. They may buy
14 a table, and it may be something in the -- it's
15 twenty, \$25,000.

16 Q And does -- Imerys is a member of the
17 PCPC, correct?

18 A They have been. I actually didn't check
19 whether they were a member this year.

20 Q All right. And have they been a
21 contributor to the DreamBall?

22 A Not that I know of.

23 Q Have they been a contributor in some
24 other way to the foundation?

1 A Not that I know of.

2 Q The -- the employees of the foundation,
3 do they -- whether they get paid on a weekly or
4 biweekly basis, do they get paid by PCPC?

5 A Right. So they're part -- they're part
6 of our ADP payroll system and the same benefit
7 plans, but the money is allocated to come from
8 their separated funds from the donations.

9 Q Okay. But their check comes from PCPC.

10 A Yes.

11 Q And their office is in the PCPC space?

12 A Yes.

13 Q And whether it's you or somebody else,
14 somebody -- some executive in administration for
15 PCPC oversees kind of the administrative things
16 for the foundation.

17 A Yes.

18 Q Okay. Next on your list is the Cosmetic
19 Ingredient Review. Have there been any changes
20 here?

21 A So the executive director, Lillian Gill,
22 retired. Bart Heldreth, who's listed as chemist,
23 was promoted to executive director. Monice is --
24 I think her title is deputy, or she's the

1 equivalent. I don't know her exact title. Ivan
2 Boyer, senior toxicologist, has left. Lillian
3 Becker is no longer there, and so then three new
4 employees have been hired to fill these slots.

5 Q Who hires these new employees?

6 A The director of -- the executive
7 director of CIR.

8 Q And is there input from PCPC?

9 A There's some input on salary range. I
10 may have met one or two of them.

11 Q Are you the -- are you the final decider
12 on how much an employee of Cosmetic Ingredient
13 Review gets paid?

14 A Me and others.

15 Q Who are the others?

16 A Kris Bogenrief, who is our CF chief
17 financial officer, would have input on that also.
18 We have salary ranges and they have a budget
19 and --

20 Q Okay. But -- so just to be clear, when
21 you're talking about you, Mark Pollak, and others
22 that have the final say on the cosmetic -- the
23 salaries on the Cosmetic Ingredient Review, the
24 others are employees of the PCPC, correct?

1 A Correct.

2 Q And the checks that the people from
3 Cosmetic Ingredient Review receive are PCPC
4 checks?

5 A Yes.

6 Q And they -- do you use a --

7 A Payroll service?

8 Q -- payroll service?

9 A Yes.

10 Q And do they get paid through the same
11 payroll service?

12 A Yes.

13 Q And is there somebody at PCPC that is
14 responsible for -- first, let me strike that.

15 Do you get paid on a weekly basis,
16 biweekly basis, monthly --

17 A Biweekly.

18 Q Okay. And is there somebody at PCPC
19 that is responsible for calling in the numbers to
20 the payroll service?

21 A Right, the accounting department.

22 Q And that would be the accounting
23 department of PCPC?

24 A Correct. They don't have any admin- --

1 CIR would not have that internal function.

2 Q Right. So the -- the employees of PCPC
3 are calling in the payrolls of the employees of
4 PCPC council, PCPC Foundation, and CIR, correct?

5 A Yes.

6 Q And you and other employees of PCPC are
7 the ones who have the final say-so on how much an
8 employee of Cosmetic Ingredient Review gets paid?

9 A Yes.

10 Q And when you gave me the numbers
11 earlier, I think -- correct me if I'm wrong, I
12 think you said there was something like 53 or 56
13 employees. Were you counting PCPC, foundation and
14 CIR?

15 A Yes.

16 Q Okay. So how many specific employees
17 are there on the PCPC council?

18 A I think it's approximately 40.

19 Q And on the foundation?

20 A So the foundation has six or seven, and
21 CIR has seven or eight.

22 Q All right. On the Cosmetic Ingredient
23 Review, who took over as senior toxicologist?

24 A He has an Asian name that I can't

1 pronounce. Sorry.

2 Q Who took over as chemist for Bart
3 Heldreth?

4 A So that -- that slot, I think is Alison,
5 and again, I don't remember her last name.

6 Q Who took over as scientific analyst for
7 Monice?

8 A Well, we didn't fill that slot. She
9 just got a promotion. It would be the replacement
10 for Lillian Becker, and it's a woman, Priya, and I
11 don't -- don't recall her last name.

12 Q And everybody else remains the same?

13 A Yes.

14 Q Does PCPC do performance reviews of its
15 employees?

16 A Most -- most departments do.

17 Q Okay. Tell me how that -- generally how
18 it works.

19 A So it's an annual system. There's a
20 template that's provided by human resources that's
21 distributed I think in January or February, and
22 the supervisor prepares a write-up and meets with
23 the people that he or she supervises, and then a
24 copy is provided to human resources.

1 Q Okay. So let's take a look at the
2 Science department as an example, okay? And let's
3 just take the senior environmental scientist, Iain
4 Davis.

5 So the template of a -- of the review
6 would be provided to his supervisor?

7 A Correct, Alex. Yeah, the senior -- the
8 EVP for Science would be responsible. She
9 basically supervises the team. I think you'll
10 find lower down that some of the managers are
11 supervising people below them. She doesn't have
12 nine direct reports. She probably has four or
13 five.

14 Q Okay. But is -- is the EVP in each
15 department ultimately responsible for the
16 performance review of each employee in their
17 department?

18 A Yes.

19 Q Okay. And is that true of the PCPC
20 Foundation?

21 A Yes.

22 Q So Louanne Roark in this case would be
23 the -- be doing the performance reviews of the
24 other six people in the foundation?

1 A Yes.

2 Q And then once those performance reviews
3 are completed, they go where?

4 A To our personnel department, human
5 resources.

6 Q Okay. And would the same be true of
7 Cosmetic Ingredient Review, that is now --

8 A Yes.

9 Q -- Bart Heldreth would do the
10 performance reviews of everybody within the CIR,
11 and then they would go to human resources at PCPC.

12 A Right.

13 Q And what generally do you do with those
14 performance reviews?

15 A I think they go in the employee's file.

16 Q Okay. And so in terms of the process,
17 it's pretty much the same for the PCPC
18 employees --

19 A Right, they're subject to all --

20 Q Let me just finish the question.

21 It's pretty much the same for the PCPC
22 employees, the foundation employees and the CIR
23 employees?

24 A Yes.

1 Q All right. And the -- these people in
2 the foundation, they -- I think you had told us
3 previously that they have offices within the PCPC
4 offices, correct?

5 A Yes. We're all on the same floor.

6 Q Right. And the same is true of the CIR?

7 A Yes.

8 Q And so the foundation is completely
9 funded by PCPC.

10 A No.

11 MR. LOCKE: Objection.

12 BY MR. GOLOMB:

13 Q Other than the outside -- the outside
14 funding that we talked about before, the
15 fundraisers, the contributions from individuals.

16 A We don't fund them at all. All the
17 money of the -- we are reimbursed by the
18 foundation, you know, even for every square foot
19 of space they occupy.

20 Q Okay. And the --

21 A I think they're a (c)(3). We're a
22 (c)(6).

23 Q Okay. The CIR is completely funded by
24 the PCPC?

1 A Yes.

2 Q There's no reimbursement there?

3 A No.

4 Q There's no outside funding there?

5 A No.

6 Q So the -- the CIR employees get paid by

7 PCPC, correct?

8 A Yes.

9 Q Their office space is paid for by PCPC?

10 A Yes.

11 Q Their office supplies are paid for by

12 PCPC?

13 A Yes.

14 Q If they have -- if they have an office,

15 they're told where to sit by somebody at PCPC?

16 A I wouldn't go that far, but it would be

17 the director -- the executive director of CIR,

18 right.

19 Q Well, when a new employee comes in and

20 they're told, This is going to be your office,

21 it's the final --

22 A He would make --

23 -- the final decision of the PCPC.

24 A Indirectly.

1 Q What do you mean "indirectly"?

2 A The executive director would make that
3 kind of decision on the space allocation.

4 Q Okay. Do you -- are there -- are there
5 regular hours at the PCPC?

6 A There's a basic workday, but there is --
7 we are supportive of flexible schedules.

8 Q Okay. And is that -- the basic workday,
9 is that in a manual for -- some sort of procedures
10 manual?

11 A We have an employee handbook, and I
12 actually don't recall whether it says -- it
13 probably does say the basic workday is 9:00 to
14 5:00.

15 Q And the -- the employee handbooks covers
16 the employees of the Cosmetic Ingredient Review?

17 A Yes.

18 MR. GOLOMB: Let's mark this No. 3.

19 (Pollak Exhibit No. 3 was marked
20 for identification.)

21 BY MR. GOLOMB:

22 Q I'm going to show you a document which
23 is marked as Pollak No. 3.

24 You've seen that before, correct?

1 A I think I have.

2 Q In fact, I think, if my memory serves me
3 right, you told me at the last deposition that you
4 prepared this.

5 A No, I wouldn't have. The accounting
6 department would have prepared it. It's possible
7 I reviewed it, but I wouldn't have the capability
8 of preparing it.

9 Q Okay. Did they prepare it at your
10 request after I asked Dr. Loretz some questions
11 about it, and she was unable to answer it, and so
12 you took it upon yourself to have this prepared?
13 Does that sound familiar?

14 A I don't recall the sequence of events.

15 Q All right. In any event, this is a -- a
16 general ledger which shows the contributions
17 between 1992 and 2009 into the Talc Interested
18 Party Task Force, correct?

19 A Yes.

20 Q And there's -- the numbers total just
21 under \$440,000, correct?

22 A Yes.

23 Q More than half of which came from
24 Johnson & Johnson and Luzenac America, which we

1 know is now Imerys, correct?

2 A Yes.

3 Q By far the largest being Johnson &
4 Johnson, correct?

5 A Yes.

6 Q Now, I had asked you some questions
7 before about the interested party task forces
8 generally and how they kind of come and go. Some
9 come and go dependent on the issue of the day as
10 it relates to that subject, correct?

11 A Yes.

12 Q And so would it be fair to conclude from
13 this ledger that the Talc Interested Party Task
14 Force was active in 1992, '93, '94, and '97, 2000,
15 2001, 2005, 2008, and 2009?

16 A Yes. However, sometimes when there are
17 contributions made, it's just because there are
18 funds that are depleted in the account. It
19 doesn't mean there's a big activity at that
20 particular time, but...

21 Q Well, by far the largest activity on
22 this was in -- 1992 was one of the most active
23 years, correct?

24 A Yes.

1 Q And --

2 A For solicitation of funds.

3 Q Okay. And are you aware that 1992 was a
4 year that Dr. Cramer authored and reported his
5 second study on the relationship between talc and
6 ovarian cancer?

7 MR. LOCKE: Objection. Beyond the
8 scope.

9 THE WITNESS: No.

10 BY MR. GOLOMB:

11 Q So you don't know one way or the other
12 as to whether it's just a coincidence that the
13 second most active year was the year that
14 Dr. Cramer's study came out?

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 THE WITNESS: I -- I don't know.

18 BY MR. GOLOMB:

19 Q Okay. And you know you're aware -- you
20 know what the NTP is?

21 A Yes.

22 Q Okay. And is it just a coincidence that
23 the year in which more than half of the funds over
24 the last -- over the 17 years was in the year that

1 the NTP was evaluating whether or not to report
2 out talc as a carcinogen?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 THE WITNESS: Again, I wouldn't have any
6 independent knowledge.

7 BY MR. GOLOMB:

8 Q Okay. So you haven't spoken to anybody
9 or reviewed any documents to prepare for your
10 deposition here today which would show that the --
11 by far the largest expenditures from the Talc
12 Interested Party Task Force were to defend itself
13 in the NTP review?

14 MR. LOCKE: Objection to form and beyond
15 the scope.

16 THE WITNESS: No, I didn't.

17 BY MR. GOLOMB:

18 Q Okay. Do you know where the money that
19 was accumulated in 2000 went?

20 A I actually do not.

21 Q Do you know who Dr. Josh Muscat is?

22 A No.

23 Q Do you know who Dr. Huncharek is?

24 A No.

1 Q Do you know who the Weinberg Group is?

2 A Yes.

3 Q Who is the Weinberg Group?

4 A They're a consulting group in Washington
5 that I know we've worked with.

6 Q Okay. And do you know whether or not
7 the Weinberg Group was retained by the PCPC to
8 defend its members in the NTP review?

9 MR. LOCKE: Objection to form and beyond
10 the scope.

11 THE WITNESS: I know the Weinberg Group
12 was involved with helping with the presentation
13 for NTP.

14 BY MR. GOLOMB:

15 Q And do you know how much of the \$245,000
16 and the \$29,000 that was collected by the task
17 force in 2000 and 2001 went to the Weinberg Group?

18 A No, I don't.

19 Q Do you know, and correct me if -- I may
20 get the name wrong, but there's a crisis
21 management company called Nichols-Denzenhall.

22 A Dezenhall, yeah.

23 Q Okay. Do you know who they are?

24 A Yes.

1 Q Who are they?

2 A So they're a crisis management and
3 public relations firm in Washington.

4 Q What is a crisis management firm?

5 A So we had started working with them
6 earlier. They help organizations if there's a --
7 if there's a lot of media attention focus on a
8 particular safety issue, for example.

9 Q And had Dezenhall ever been hired by the
10 PCPC before 2000?

11 A Yes.

12 Q For what issues?

13 A There was a big issue in -- earlier in
14 the '90s about multiple chemical sensitivity
15 involving fragrances.

16 Q Anything related to talc?

17 A I know he made a proposal for doing some
18 work on talc, and I don't recall where that went
19 or how.

20 Q Okay. So do you know if or how much of
21 the money collected by the Talc Interested Party
22 Task Force went to the Dezenhall group as a -- for
23 crisis management fees in 2000 and 2001?

24 MR. LOCKE: Objection. Form, beyond the

1 scope.

2 THE WITNESS: And I don't know.

3 BY MR. GOLOMB:

4 Q And none of the documents that you
5 reviewed to prepare for your deposition here today
6 assisted you in that way?

7 A So, again, I -- if I recall,
8 Nichols-Dezenhall was involved perhaps with a
9 focus group. I know they had some involvement
10 with the issue and made a proposal, but I...

11 Q Okay. If you assume for the purpose of
12 my question that both the Weinberg Group and
13 Nichols-Dezenhall were both hired around the time
14 of -- in 2000 when the NTP was reviewing whether
15 or not to include talc as a carcinogen, I want you
16 to assume that to be true for the purposes of my
17 question.

18 So as you sit here today, you've never
19 read the Weinberg report as it relates to talc?

20 MR. LOCKE: Objection. Beyond the
21 scope.

22 THE WITNESS: I don't recall ever seeing
23 it.

24 BY MR. GOLOMB:

1 Q And you haven't reviewed the Dezenhall
2 report as it relates to talc?

3 MR. LOCKE: Objection. Beyond the
4 scope.

5 THE WITNESS: I don't even know if there
6 is a report.

7 BY MR. GOLOMB:

8 Q Okay. Is it -- if Dezenhall or Weinberg
9 had been hired to -- to do their work in -- with
10 respect to some other ingredient that may affect
11 some other member, in the scope and course of your
12 employment, is that something that you would see?

13 A Possibly at the time, but it's so long
14 ago, I can't recall what I did read and I didn't
15 read. I mean, we had previous relationships with
16 both organizations on -- on other matters.

17 Q Okay. So, as you sit here today, you
18 just don't recall one way or the other as to
19 whether or not you read those reports as they
20 relate to the association between talc and ovarian
21 cancer?

22 MR. LOCKE: Objection. Beyond --

23 BY MR. GOLOMB:

24 Q Is that correct?

1 MR. LOCKE: Beyond the scope.

2 THE WITNESS: I may -- I probably would
3 not have read a report that would be -- or a
4 submission to the NTP at that time.

5 BY MR. GOLOMB:

6 Q Would you -- would you -- as part of
7 your job, would you have known how much these
8 entities were paid?

9 A At the time I would have known it, but I
10 don't recall now this many years later what --
11 what was discussed.

12 Q Okay. What's the purpose of the PCPC?

13 A So we are the national trade association
14 that represents cosmetic, toiletry and fragrance
15 manufacturers and distributors in the U.S., and
16 providing them with technical reg- -- and
17 regulatory information to represent them on
18 government affairs, public affairs, and to work to
19 obtain international uniformity on cosmetic
20 regulation.

21 Q Now, does either you or somebody at the
22 PCPC have regular dealings with the FDA?

23 A Yes.

24 Q Now, just looking at your list of

1 members, they're all -- they're all cosmetic
2 companies of one -- one form or another, correct?

3 A Right. The -- yes.

4 Q And many of them are, in addition to
5 manufacturing and distributing cosmetics, they
6 also manufacture and distribute pharmaceuticals,
7 correct?

8 A Some do, yes.

9 Q Right. As an example, Johnson &
10 Johnson.

11 A Yes.

12 Q Right. And you're aware, are you not,
13 that the -- the FDA requirements as they relate to
14 pharmaceuticals are different than the FDA
15 requirements --

16 A Yes.

17 Q -- as they relate to cosmetics, correct?

18 MR. LOCKE: Objection. Beyond the
19 scope.

20 THE WITNESS: But I -- I'm aware of
21 that, yes.

22 BY MR. GOLOMB:

23 Q Just very generally, what -- based on
24 your many years of working at PCPC, how would you

1 explain the difference?

2 MR. LOCKE: Objection.

3 BY MR. GOLOMB:

4 Q Between the role of the FDA as they
5 relate to cosmetics versus pharmaceuticals.

6 MR. LOCKE: Objection. Beyond the
7 scope.

8 THE WITNESS: Pharmaceuticals are much
9 more -- there's a lot more regulation, and there's
10 premarket approval of pharmaceuticals. There's
11 not premarket approval of cosmetics.

12 BY MR. GOLOMB:

13 Q Is it fair to say that cosmetics are
14 self-regulated?

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 THE WITNESS: One -- one could say that,
18 but there are FDA -- a number of FDA regulations
19 involving packaging, labeling, ingredient
20 substantiation.

21 BY MR. GOLOMB:

22 Q Okay. And if you had read some of the
23 same documents that I read in preparation for the
24 deposition here today, it is -- as it relates to

1 regulation, it is the goal of the PCPC to maintain
2 that self-regulatory status, correct?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 THE WITNESS: We would have earlier said
6 that, but now we feel that our -- the goal is to
7 modernize regulation. People have accepted a
8 larger role for government agencies.

9 BY MR. GOLOMB:

10 Q What do you mean by that?

11 A I think there's a consumer expectation,
12 and we -- until perhaps ten years ago, we did use
13 the term "self-regulated" a lot. But we felt that
14 was no longer appropriate and that we needed to
15 work on modernizing regulation. For example, the
16 Food, Drug and Cosmetic Act which governs
17 cosmetics hasn't been changed since 1938.

18 Q Well, have you been on your website?

19 A Yes.

20 Q Have you been on your website to look at
21 it to prepare for your deposition here today?

22 A No.

23 Q Would it surprise you to see that on
24 your -- on your website they still refer to

1 self-regulation as a -- as a goal and a mission of
2 the PCPC as it relates to cosmetics?

3 MR. LOCKE: Objection to form.

4 THE WITNESS: That's -- I mean it's
5 possible. We're actually -- as I said earlier,
6 we're in the process of updating the website
7 anyway.

8 BY MR. GOLOMB:

9 Q Okay. So --

10 A But that probably is one area that's
11 being addressed.

12 Q So the -- the thinking as to the
13 self-regulatory status of the company began about
14 ten years ago, you said, but you just haven't
15 gotten to the website yet?

16 MR. LOCKE: Objection to form and beyond
17 the scope.

18 THE WITNESS: I -- I think, though, we
19 talk about modern -- you know, the goal of
20 modernizing government regulation.

21 BY MR. GOLOMB:

22 Q And -- and what do you mean by that?

23 A Updating federal regulation. We believe
24 in a strong regulatory process. FDA regulations

1 should be the gold standard, and we're hoping that
2 other regulatory bodies worldwide will model
3 themselves on FDA.

4 Q Well, and is that because the FDA
5 doesn't regulate cosmetics?

6 MR. LOCKE: Objection to form and beyond
7 the scope.

8 THE WITNESS: As I said, they -- there
9 is regulation, you know, involving how companies
10 have to label and package and disclose their
11 ingredients.

12 BY MR. GOLOMB:

13 Q Okay. What is your understanding of how
14 the FDA regulates labeling?

15 MR. LOCKE: Objection to -- beyond the
16 scope.

17 THE WITNESS: There's the Fair Package
18 Labeling Act, but it's really not my area of
19 responsibility. I'm just telling you what --
20 what -- more common knowledge.

21 BY MR. GOLOMB:

22 Q Okay. And -- well, is the -- is the
23 common knowledge based on what the employees of
24 the PCPC and its members would like it to be or is

1 it based on the actual regulation?

2 A It's based on the actual regulation.

3 Q Okay. Well, when was the last time you
4 looked at the actual regulation?

5 MR. LOCKE: Objection.

6 THE WITNESS: I don't recall.

7 MR. LOCKE: Beyond the scope.

8 BY MR. GOLOMB:

9 Q But you agree that whatever the
10 regulation is under the CFR is what's -- what is
11 binding on the company members --

12 A Yes.

13 Q -- of the PCPC, correct?

14 A Yes.

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 MR. GOLOMB: Want to take about a
18 ten-minute break?

19 MR. LOCKE: Sure.

20 THE VIDEOGRAPHER: The time is
21 10:45 a.m., and we're going off the record.

22 (Recess.)

23 THE VIDEOGRAPHER: The time is
24 11:01 a.m., and we're back on the record.

1 BY MR. GOLOMB:

2 Q Mr. Pollak, do you have Pollak No. 3
3 in front of you there? This is the --

4 A Yes.

5 Q -- the ledger of the --

6 A Yes.

7 Q -- contributions.

8 Before I was asking you some questions
9 about whether or not certain entities received
10 payment, and you didn't know the answer to that.

11 And so my question to you is, who -- who
12 would know?

13 A Well, I assume Linda Loretz is covering
14 this, and the accounting department that produced
15 the document.

16 Q Okay. So your assumption is if I asked
17 her about the same people, Dr. Muscat,
18 Dr. Huncharek, Weinberg Group, et cetera, the
19 people I asked you about, and there's some
20 additional ones, that Ms. Loretz would be the one
21 to say, you know, in 2000 we received \$245,000 in
22 contributions from various task force members, and
23 I think Dr. Loretz would know the answer to how
24 much went to each of these individual entities; is

1 that correct?

2 A I assume so, yes.

3 Q Okay. We were also -- let's just talk
4 about -- you were saying about this -- although
5 the website hasn't been updated, this ten-year
6 transition going into self-regulatory based on
7 what the consumer wants.

8 First of all, who -- who -- which of the
9 employees that we talked about -- employee or
10 employees that we talked about on that
11 organizational chart would be the one who would be
12 most often liaisioning with the FDA?

13 A So it would depend on the issue. Tom
14 Myers on a lot of regulatory issues would -- or
15 Emily would be the primary --

16 Q Do you have -- I'm sorry. Do you have
17 the organizational chart in front of you?

18 A Sure. So some of it would be through
19 Science, some of it would be through legal, and
20 then some of it would be through government
21 relations, depending on the issue.

22 Q Okay. Let's -- let's talk about legal.

23 A Okay.

24 Q As it relates to the issue of talc, who

1 would be the person who would be the -- most often
2 liaisioning with the FDA?

3 A So I -- I don't think anyone from the
4 legal department did.

5 Q Okay. What about Government Affairs?

6 A They definitely did not.

7 Q You described for me before the
8 Government Affairs department as lobbying. So
9 you're saying that your lobbyists are not talking
10 to the FDA as it relates to talc?

11 A Correct.

12 Q And how is it that you're so sure about
13 that?

14 A I would have -- the government would be
15 more in the context of proposed regulation or
16 mainly for Government Affairs involving proposed
17 legislation.

18 Q Okay. And as -- as this ten-year
19 transition has been undergoing, have there -- has
20 there been legislation proposed?

21 A Yes.

22 Q Okay. And tell me about the
23 legislation.

24 A So this has started perhaps in 2008, an

1 effort to update and modernize the Food, Drug and
2 Cosmetic Act, to make some provisions of the
3 Voluntary Cosmetic Reporting Program mandatory, to
4 have FDA promulgate good manufacturing practices
5 for cosmetics, to formalize the Adverse Event
6 Experience Reporting System, things like that, and
7 then an ingredient review program.

8 Q Adverse event reporting for cosmetics?

9 A Mm-hmm. That's -- had initially been
10 part of the Voluntary Cosmetic Reporting Program,
11 so then that was eliminated around 1999.

12 Q Who was it that -- who is it at PCPC
13 that is responsible for that legislation?

14 A Well, there are a number of people who
15 work on it, but it would be John Hurson is the
16 EVP.

17 Q And he's EVP of what department?

18 A Govern -- Government Affairs.

19 Q Now, so you're -- you're saying that
20 John person -- I mean, John Hurson is -- is
21 responsible for this legislation, but he does not
22 have contact with the FDA?

23 A He has contact in the FDA. We've had
24 meetings regarding -- not recently, but regarding

1 the proposed legislation and what FDA -- how they
2 would handle it or how they would view it and what
3 would be acceptable to them.

4 Q And is the proposed legislation in
5 print?

6 A Yes. There's a -- it's been introduced
7 in the Senate.

8 Q Who has it been introduced by?

9 A Senators Feinstein and Collins.

10 Q That's SB what?

11 A I don't recall.

12 Q When was it first introduced?

13 A 2016, is it -- but within the last two
14 years.

15 Q And how did -- was it Mr. Hurson who got
16 Senators Feinstein and Collins aboard?

17 A Well, it was a broader effort, but yes.

18 Q Broader effort by who?

19 A Well, Lezlee Westine would have been
20 involved.

21 Q Was there involvement by some of your
22 members?

23 A Possibly, but I wouldn't -- I mean,
24 Senators Feinstein and Collins introduced the bill

1 on their own. We had been working with FDA on a
2 proposal that ended up in a stalemate, and then
3 Senator Feinstein decided to take the lead.

4 Q Does PCPC make contributions to
5 individual congressional members' campaigns?

6 A So there is a political action committee
7 and contributions would be made through that.

8 Q What's the name of the political action
9 committee?

10 A I think it's the PCPC Political Action
11 Committee.

12 Q And are they run out of the PCPC office?

13 A Yes.

14 Q And who is responsible for the day to
15 day of the PCPC PAC?

16 A So the federal PAC would be John Hurson.

17 Q So the same person who is responsible
18 for the proposed legislation is also responsible
19 for the PAC that maintains a political action
20 committee that makes contributions, in this case
21 to Senator Feinstein and Senator Collins?

22 MR. LOCKE: Objection to form.

23 THE WITNESS: Possible- -- I don't know
24 if -- I think --

1 BY MR. GOLOMB:

2 Q Are there -- are there separate
3 documents, financial documents for the PCPC PAC
4 that are maintained --

5 A Yes.

6 Q -- within the PCPC?

7 A Yes.

8 Q And is John Hurson the person that would
9 know the most about who contributed what to whom
10 and how much the PCPC contributed to which
11 legislators?

12 A Right. And there are annual filings
13 that I think are public.

14 Q And do you know what committee -- well,
15 strike that.

16 Do you know what -- what is the status
17 of the bill?

18 A Well, it's -- it's being considered in
19 the Senate Health, Education, Labor and Pensions
20 Committee.

21 Q Who's the chairman of that committee?

22 A Lamar Alexander.

23 Q Who is the minority leader?

24 A I don't recall.

1 Q Do you know who else --

2 A Maybe Patty Murray. I don't recall.

3 Q Do you know approximately when it --
4 approximately when it went to the Senate Health
5 Committee?

6 A So this is -- this year they're looking
7 at a draft.

8 Q And do you know which senators while
9 this is -- while this is pending before the
10 Senate, do you know which members received funds
11 from the PCPC PAC in the way of contributions?

12 A No, I don't.

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 BY MR. GOLOMB:

16 Q Do you know the names of any of the
17 sponsors to the bill?

18 A No.

19 Q Are there -- are there written reports
20 from Mr. Hurson from time to time about the status
21 of the legislation?

22 A Yes. We -- we report on it at our board
23 meetings.

24 Q How often are your board meetings?

1 A Three times a year.

2 Q When was the last time you had a board
3 meeting?

4 A May 31.

5 Q And did you receive a status of the
6 bill?

7 A Yes.

8 Q What was the status at that time?

9 A Approximately what I told you in the
10 last few minutes. It's being considered in -- in
11 the Senate Health Committee, and they're -- we're
12 hoping that Senator Feinstein and Senator
13 Alexander will get together and reach agreement,
14 and so far they haven't.

15 Q What -- is Senator Feinstein on the
16 Senate Health Committee?

17 A I think so, but I -- I don't know.

18 Q Okay. Do you know whether she's the --
19 the minority leader on that --

20 A I don't think she is.

21 Q -- committee?

22 Do you know why it is that Mr. Hurson
23 went to Senator Feinstein for -- to seek
24 co-sponsorship?

1 A He --

2 MR. LOCKE: Objection to form.

3 THE WITNESS: He didn't. As I said,
4 she -- she decided to introduce it on her own.

5 BY MR. GOLOMB:

6 Q Okay. And does the PCPC hire outside
7 lobbyists from time to time?

8 A Yes.

9 Q And do they hire outside lobbyists to
10 handle certain issues?

11 A We have a lobbying firm on retainer.

12 Q Who is that?

13 A Mehlman Vogel Castagnetti Thomas or --
14 they may have changed the name, but that's --

15 Q I'm sorry, Melvin?

16 A Mehlman.

17 Q Mehlman.

18 A M-E-H-L-M-A-N.

19 Q Mark Mehlman?

20 A No, Bruce Mehlman. No relation.

21 Q What was the second name?

22 A Well, they -- I know David Castagnetti
23 is one of the other named partners. They changed
24 their name, and I don't want to give you the

1 wrong --

2 Q Okay. And do you know who is on the --
3 from the outside lobbying team that is responsible
4 for this senate bill?

5 MR. LOCKE: Objection to form and beyond
6 the scope.

7 THE WITNESS: I -- I wouldn't say the
8 person -- we work with Bruce Mehlman and get his
9 advice.

10 BY MR. GOLOMB:

11 Q When was the last time you spoke with
12 Bruce Mehlman about this bill?

13 A I saw him at a meeting in the last few
14 weeks.

15 Q And did you talk about this bill?

16 A Yes.

17 Q Was that the purpose of the meeting?

18 A Yes.

19 Q Okay. When you say you have them on
20 retainer, how much is the retainer?

21 A I think it is \$25,000 a month.

22 Q And where does the money come from?

23 A From our general operating budget.

24 Q Are outside lobbyists hired from time to

1 time to deal with specific issues related to a
2 specific task force?

3 A I wouldn't say a specific task force.
4 Sometimes it's a specific piece of legislation.

5 Q Are there -- are there times when the
6 funding of the outside lobbyists, like in the case
7 of Mehlman and his \$25,000 a month, are there
8 times when the money would come from an individual
9 task force rather than the operating?

10 A I don't think so.

11 Q What do you hope to accomplish through
12 the passage of this bill?

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 THE WITNESS: As I said, you know, the
16 goal is modernize federal regulation and make
17 mandatory a number of things that are currently
18 voluntary; have GMPs as part of the mandatory
19 regulation so that the FDA is considered the gold
20 standard as far as cosmetic regulation.

21 BY MR. GOLOMB:

22 Q Give me an example of something that is
23 currently now mandatory that you want to make -- I
24 mean that is now voluntary that you want to make

1 mandatory as part of this bill.

2 MR. LOCKE: Objection. Beyond the
3 scope.

4 THE WITNESS: Currently, companies --
5 there's a voluntary program to -- for companies to
6 provide locations of their manufacturing
7 facilities as well as ingredient -- the formulas
8 for cosmetic products, and they do register those
9 with FDA, but it's not mandatory.

10 BY MR. GOLOMB:

11 Q And why do you want that to be mandatory
12 for your members?

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 THE WITNESS: Because we think it's a
16 stronger regulatory system.

17 BY MR. GOLOMB:

18 Q Okay. Well, on your website you refer
19 to the need to maintain a self-regulatory system,
20 so which common sense-wise doesn't seem to jibe.

21 So tell me -- I mean you mentioned to me
22 before that there's been this ten-year transition,
23 but it's still on your website.

24 A Right. We still -- for example, the

1 Cosmetic Ingredient Review program is the linchpin
2 of our self-regulatory philosophy. So -- and
3 we're not -- we're not disavowing that. That's
4 going to be a key.

5 Q And when you say that's the linchpin of
6 your self-regulatory process, what do you mean?

7 A Currently there's no FDA premarket
8 review of cosmetics or cosmetic ingredients. The
9 proposed legislation would have set up an
10 ingredient review process, but we have this
11 self-regulatory program for 40 years where we
12 review the -- the data on the safety of cosmetic
13 ingredients, and the expert panel makes
14 recommendations as far as determination of the
15 safety category.

16 Q So in part, are you saying that you --
17 you have this CIR, number one, to maintain
18 independence from the PCPC and while at the same
19 time strengthening the self-regulatory process?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: I'm not sure I would
22 characterize the legislation as strengthening the
23 self-regulatory process.

24 BY MR. GOLOMB:

1 Q I -- I didn't say -- I'm sorry.

2 A Okay.

3 Q I didn't say anything about the -- I'm
4 talking about the CIR.

5 A Okay.

6 Q You said it's the linchpin of your
7 self-regulatory process, and my question to you
8 was, do you -- you've -- this linchpin of the
9 self-regulatory process, you review that as
10 some -- something independent from the PCPC?

11 MR. LOCKE: Objection to form.

12 THE WITNESS: Yes. I mean, the -- the
13 expert panel is totally separate.

14 BY MR. GOLOMB:

15 Q The expert panel which is selected by
16 employees of the PCPC, correct?

17 A No.

18 Q You have -- there's a CIR board of
19 directors?

20 A No.

21 Q There -- is there a CIR board of some
22 sort?

23 A No, there's a CIR steering committee
24 that's in the procedures that are on their

1 website, and the CIR expert panel members are --
2 there's a nominating process. Anybody -- any
3 member of the public can nominate someone for --
4 to be considered for an expert panel member.
5 There are other ways of soliciting nominations,
6 and the ultimate determination is made by the
7 steering committee.

8 Q How many members of the steering
9 committee are there?

10 A Seven.

11 Q And is there a chairman of the steering
12 committee?

13 A Yes.

14 Q And who is the chairman of the steering
15 committee?

16 A So the chairman of the steering
17 committee is the CEO of PCPC.

18 Q All right. And so that's your -- that's
19 your view of independence, to have the -- the --
20 the chairman of the company that's funding the
21 organization, in this case the CIR, be the
22 chairman of what it is they're funding?

23 MR. LOCKE: Objection to form.

24 THE WITNESS: The steering committee

1 also includes a representative from the Society of
2 Toxicology, the American Academy of Dermatology,
3 there's a representative from the Consumer
4 Federation of America. It's, you know, all -- all
5 the stakeholders involved with -- in the program
6 have a say.

7 BY MR. GOLOMB:

8 Q Yeah. And all those stakeholders are --
9 are selected to serve as members of the steering
10 committee by executives from PCPC, correct?

11 MR. LOCKE: Objection. Form.

12 THE WITNESS: No. The -- in fact, we
13 just -- we're in the process of getting a new
14 toxicologist, and there is -- you know, the
15 Society of Toxicologists is putting forth some
16 recommendations on people, and it will be
17 considered at the next steering committee meeting.

18 BY MR. GOLOMB:

19 Q Okay. Can we go to Exhibit 11, please.

20 MR. DONATH: 11?

21 MR. GOLOMB: 11.

22 (Pollak Exhibit No. 11 was marked
23 for identification.)

24 BY MR. GOLOMB:

1 Q What you have in front of you is Imerys
2 document 118791, and if you look at the bottom
3 half, it says: "Part B. The Cosmetic Ingredient
4 Review Steering Committee and Staff."

5 A Mm-hmm.

6 Q Are you familiar with this document?

7 A Yeah. I mean it's -- it's an old
8 version of the procedures.

9 Q Okay. And when you say old, how old is
10 it?

11 A Well, it's at least a few years old
12 because it still has on -- on there 1101 17th
13 Street, and we moved four-and-a-half years ago.

14 Q Okay. Well, if you look at Section 10,
15 it's defined as "Organization of the Cosmetic
16 Ingredient Review, "and look at (a)(1) through
17 (6) --

18 A Mm-hmm.

19 Q -- other than the address, has any of
20 that changed substantively?

21 A Yeah, so the only other change would be
22 in (a)(1), the president and CEO can designate the
23 chief operating officer as the chair of the
24 steering committee.

1 Q Okay. And so for the record, this is
2 the organization of the Cosmetic Ingredient
3 Review. And it says: "The general policy and
4 direction for Cosmetic Ingredient Review shall be
5 given by a steering committee. A quorum of the
6 steering committee shall consist of five members.
7 Any member before the steering committee shall be
8 decided by a majority vote of the CIR members
9 present at the time, except where otherwise
10 specifically provided in these procedures. The
11 steering committee shall consist of the following
12 members."

13 First of all, did I read that correctly
14 so far?

15 A Yes.

16 Q And is this document, is this from the
17 PCPC or from the Cosmetic Ingredient Review?

18 MR. LOCKE: Objection. Just to the
19 extent to -- I want to state for the record this
20 is an old version. We have and can give you a
21 current version if you want.

22 You can answer the question.

23 THE WITNESS: Right. So as he said, I
24 mean I reviewed the procedures on their website

1 yesterday.

2 BY MR. GOLOMB:

3 Q Is this -- what you have in front of
4 you, is this a procedure from the CIR or a
5 procedure from the PCPC?

6 A It's on the -- it's on the CIR website.

7 Q Okay. And is the CIR website distinct
8 from the PCPC website?

9 A Yes.

10 Q And who -- who actually -- who is the
11 webmaster of the CIR website?

12 A So that would be both Bart and Kevin
13 Fries, who is on their organization chart.

14 Q Okay. On the organization chart of the
15 CIR?

16 A Yes.

17 Q And they -- they're both paid employees
18 of the PCPC, correct?

19 A Yes.

20 Q All right. And so this lists six
21 members of the steering committee. "The president
22 and CEO of the council" -- by that it means the --
23 the PCPC council, correct?

24 A Yes.

1 Q -- "who shall serve as the chair of the
2 steering committee." Right?

3 A Yes.

4 Q So the chair of the steering committee
5 for the CIR is the president and CEO of PCPC.

6 A Right. And the revision is that the
7 chief operating officer can serve as the chair.

8 Q In addition to the president and CEO or
9 instead of?

10 A Instead of.

11 Q And then it says: "A dermatologist who
12 shall represent the American Academy of
13 Dermatology."

14 A Mm-hmm.

15 Q Correct?

16 A Yes.

17 Q And how is that person selected?

18 A Well, the American Academy of
19 Dermatology nominated Dr. Wilma Bergfeld, who
20 serves as the chair of the expert panel also.

21 Q And does --

22 A She's the former president.

23 Q Does the -- does the CIR have final say
24 on whether -- who that member of the American

1 Academy of Dermatology may be?

2 A Well, the steering committee does.

3 Q Right. The steering committee that's
4 chaired by the --

5 A Right.

6 Q -- president and CEO or COO of --

7 A Correct.

8 Q -- the PCPC.

9 And is the same true of the
10 toxicologists, that is that the PCPC has the final
11 say?

12 MR. LOCKE: Objection to form.

13 THE WITNESS: The steering committee
14 does.

15 BY MR. GOLOMB:

16 Q All right. And the -- the chair of
17 the -- it says: "(4) The chair of the council's
18 CIR Science and Support Committee." Who is that?

19 A So I actually -- the position may be in
20 transition. The person before was -- was Jack
21 Linard, but I don't know if we consider him --
22 it's the vice chair of SAC Exec, Espe Troyano from
23 Proctor & Gamble.

24 Q Okay. Well, whoever the individual is,

1 the chair of the council's CIR Science and Support
2 Committee are PCPC employees, correct?

3 A No.

4 Q Who are they?

5 A I just said she's Espe Troyano from
6 Procter & Gamble.

7 Q Okay. And they are a member of the -- a
8 dues paying member of the PCPC?

9 A Yes.

10 Q And the council executive vice president
11 for Science --

12 A Right.

13 Q -- when you refer to the council, you're
14 referring to the PCPC?

15 A Yes.

16 Q Okay. An employee of the PCPC is the
17 fifth member of this steering committee.

18 A Yes.

19 Q And then a consumer representative who
20 shall represent the Consumer Federation of
21 America, how is that person selected?

22 A The Consumer Federation of America
23 nominates someone.

24 Q And then this steering committee has the

1 final say on who that will be?

2 A Mm-hmm.

3 Q Yes?

4 A Yes.

5 Q And from time to time is the person who
6 is actually appointed to the committee some --
7 somebody who is different than the consumer
8 representative that may be nominated by the
9 Consumer Federation of America?

10 A Most of the time it's the same person.

11 Q But you said "most of the time." Not
12 all the time.

13 A There may have been -- I don't know in
14 the past whether there's ever been someone
15 different. It probably has always been the same
16 one, but it doesn't have to be.

17 Q Okay. You -- you referred to -- when I
18 was asking you about the legislation before, you
19 talked about board meetings that were held three
20 times a year, the most recent one was May 31st.

21 A Yes.

22 Q Those are board meetings of the PCPC?

23 A Yes.

24 Q And are there minutes of those board

1 meetings?

2 A Yes.

3 Q Who maintains those minutes?

4 A I do.

5 Q Did you review those -- any of those
6 minutes to help prepare you for your deposition
7 today?

8 A No.

9 Q Where are those board meetings held?

10 A Most of the time they're in New York
11 City. We have a board meeting in conjunction with
12 our annual meeting, which is usually held in
13 Florida. So two of the three are in New York.

14 Q Let's talk about the PCPC relationship
15 with -- with J&J. We've already talked about
16 their contributions to the task force.

17 They're also a member of the PCPC,
18 correct?

19 A Correct.

20 Q And as I understand from your website,
21 there are approximately 600 members?

22 A Right, including the associate members
23 who are the suppliers.

24 Q Now, is -- has that number been updated

1 over the last ten years or is that a ten-year-old
2 number?

3 A It's approximately the same. I mean, in
4 a given year we may be higher than 600 or lower --
5 but it's -- it's approximately the same over
6 the --

7 Q And does the website get updated --

8 A Yes.

9 Q -- on an annual basis to -- to show the
10 numbers?

11 A We -- we don't put an exact number
12 because at any given time during the year, the
13 number may be higher or lower. Sometimes we have
14 608, sometimes we have 592. So that's why we say
15 approximately 600.

16 Q Okay. And I would imagine that there's
17 information on your website that changes more than
18 once a year.

19 A Oh, yeah.

20 Q Okay. And -- and when information
21 becomes -- when there's new information that may
22 be relevant to the website, the website is
23 updated?

24 A Yes.

1 Q And so -- I'm sorry, I may have asked
2 you this already, but the -- who is the -- kind of
3 the webmaster of the PCPC website?

4 A So currently it's Natasha Clover. But
5 we are -- as part of the website redesign process,
6 Jamie Kirk, who is in Public Affairs, will also be
7 working with her on updating features on the
8 website.

9 Q And does the website have -- is there a
10 blog on the website?

11 A No.

12 Q Is there information on the website that
13 changes or is added on a weekly basis?

14 A Could be, because we have different
15 meetings and events posted that way. And then if
16 we do a press release, but the -- the press
17 releases wouldn't be -- most of the time wouldn't
18 be more than once a month.

19 Q And the -- the -- is there a roster of
20 the members of the PCPC somewhere on the website?

21 A Yes.

22 Q And I imagine that changes from time to
23 time?

24 A Yes.

1 Q And when -- when -- when that roster
2 changes from time to time, is it changed on the
3 website?

4 A Yes.

5 Q What other kinds of things are changed
6 on a, you know, regular, weekly, monthly,
7 bimonthly basis on the website?

8 A So on the public website, that -- that's
9 the majority of it would be involving meetings and
10 upcoming events, webinars.

11 Q Okay. So as I understand it from your
12 previous deposition, there are two different kinds
13 of members; is that correct?

14 A Right.

15 Q And what are they?

16 A Active members are manufacturers and/or
17 distributors of finished products. Associate
18 members are the suppliers to them.

19 Q Okay. And so for our purposes, J&J is
20 an active member?

21 A Yes.

22 Q And Imerys --

23 A Would be an --

24 Q -- if they're still a member --

1 A Right, would be an associate.

2 Q -- is an associate member.

3 And how -- how's their dues structure
4 determined?

5 A Okay. So for active members, dues are
6 on a sliding scale based on their U.S. sales of
7 cosmetics, toiletries and fragrances.

8 The associate members has different
9 ways -- for Imerys, for an ingredient supplier, it
10 is a sliding scale based on their U.S. sales of
11 ingredients to the cosmetics industry.

12 Q So --

13 A With a -- with a cap on what they would
14 pay.

15 Q Okay. And so what did -- what did J&J
16 pay for membership last year?

17 A If I recall, it was a little -- it was
18 in the \$490,000 range.

19 Q Is there any company that pays more than
20 them?

21 A Yes.

22 Q Who?

23 A Well, it's considered confidential
24 information we tell companies on the dues form.

1 There are at least five companies that pay more.

2 Q And out of those five companies, what --
3 what's the highest dues amount?

4 A I think the -- our largest member is
5 paying over 1.1 million a year now. The second
6 largest would be 900-something, and then two
7 companies in the 700s and one in the 600s.

8 Q And has J&J been a member at least since
9 you've been with the company?

10 A Yes.

11 Q And again, that's how many years?

12 A Thirty-five.

13 Q And if we looked at a -- if we looked at
14 a graph over the last 35 years, approximately how
15 much on an annual basis does J&J pay?

16 MR. LOCKE: Do you mean by percentage?

17 MR. GOLOMB: No. He gave me --

18 THE WITNESS: So they -- they --

19 BY MR. GOLOMB:

20 Q I'm sorry, let me be clear.

21 You gave me an amount of \$490,000 for
22 last year, and so if we look back 35 years, has
23 that been a pretty steady number? Has it gone --
24 has it fluctuated?

1 A It's gone up substantially.

2 Q From what to what?

3 A I think they -- in the '80s they
4 probably paid in the \$40,000 range -- forty,
5 50,000. They were a much smaller -- much smaller
6 company in this space, and during that time they
7 acquired a lot of other major brands that they pay
8 dues on. For example, Neutrogena cosmetics,
9 Aveeno, Listerine mouthwash, et cetera.

10 Q And when did that change?

11 A A different -- different year. I don't
12 know which acquisition was which year.

13 Q But you said in the '80s, they were
14 paying about forty to \$50,000 a year, and --

15 A Right. And starting in the '90s, they
16 had -- there were a series of acquisitions.

17 Q And were they -- so what were they
18 paying? Just generally, and we're not holding you
19 to --

20 A And, again, there have -- there have
21 been some dues rate increases. But I would say
22 ten years ago, they were probably paying two, 250.

23 Q Okay. And in the last ten years?

24 A I think their dues have gone up because

1 they're -- the -- the number of brands they're
2 paying on has increased in the U.S.

3 Q Is it fair to say that over the last 30
4 years that, just using your kind of loose range of
5 numbers, that J&J has paid in excess of \$15
6 million in -- in dues?

7 A I think that's --

8 Q Does that sound about right?

9 A I think that's probably on the high
10 side.

11 Q Well, what would you say?

12 A If -- I would say the average would be
13 no higher than \$200,000 a year, and probably less.
14 So for 30 years, doesn't that put us below
15 6 million?

16 Q And then that doesn't cover what they
17 paid into the task force, correct?

18 A Yes. That's separate.

19 Q Right. And -- and any other task force
20 they may be contributing into that we haven't
21 talked about.

22 A Right.

23 Q And do we know whether or not there are
24 other task forces that they're involved in?

1 A Yes, there are.

2 Q How many?

3 A I don't know how many, but I know they
4 would have made substantial contributions to the
5 sunscreen task force because that's a major
6 category for them.

7 Q When you say "major contribution," how
8 much are we talking about?

9 A 100,000, 200,000. I don't recall.

10 Q And how long has that been active --

11 A Sunscreen task force?

12 Q Yeah.

13 A I'd say 20 years.

14 Q And have they been paying a hundred to
15 \$200,000 --

16 A No, it's not --

17 Q -- for 20 years?

18 A It's not an annual assessment. Again,
19 it's as needed to fund the activities, and there
20 are not solicitations every year.

21 Q How many active years have there been
22 over the last 20 years for the sunscreen
23 committee?

24 A I really don't know off the top of my

1 head.

2 Q Is it more than half?

3 A Probably.

4 Q Okay. Who is the person -- if you know,
5 who is the person from J&J who is the main contact
6 with the task -- the Talc Interested Party Task
7 Force?

8 MR. LOCKE: Objection. Beyond the
9 scope.

10 THE WITNESS: I don't know.

11 BY MR. GOLOMB:

12 Q Let's talk a little bit about Imerys and
13 their -- their contributions, both to the task
14 force as well as to the PCPC.

15 Have they been members as long as
16 you've -- whether or not it was Imerys, Luzenac,
17 Rio Tinto, have they been members since you've
18 been around?

19 MR. DONATH: Objection to the form.

20 THE WITNESS: Probably, but I -- I don't
21 have independent knowledge. I did not check that.

22 BY MR. GOLOMB:

23 Q Okay. And how much in dues did they pay
24 last year?

1 A I would -- it was certainly under
2 \$10,000, and it may have been a few thousand.

3 Q And that is exclusive of whatever amount
4 they may have contributed to the task force?

5 A Yes.

6 Q And has their -- their -- their dues
7 structure been pretty straight --

8 A Again, there's been some dues rate
9 increases, but it's not dramatically different
10 over the years.

11 Q What -- what would it have been on the
12 low end?

13 A 2,000. I don't know.

14 Q Okay. And you know who the National
15 Cancer Institute is, correct?

16 A Yes.

17 Q And does the PCPC have communications
18 from time to time with the National Cancer
19 Institute?

20 A Not that I'm aware of. We may be on a
21 distribution list that we receive something from
22 them, but I'm not aware of any particular
23 relationship.

24 Q Okay. If --

1 MR. LOCKE: Let me just -- we prepared a
2 document based on some of the questions for the
3 entities that were listed on the notice, and so we
4 just put the financial portion, which is what
5 Mr. Pollak would be testing -- testifying about
6 on here.

7 MR. GOLOMB: All right. What exhibit
8 are we up to, putting 11 aside?

9 THE REPORTER: Four.

10 MR. GOLOMB: Four? Okay, 4.

11 (Pollak Exhibit No. 4 was marked
12 for identification.)

13 MR. GOLOMB: Does he have a copy to --

14 MR. LOCKE: I'll give you a copy.

15 I tell you what, just so we keep the
16 record clear, why don't you give him that copy,
17 and I'll give you this copy.

18 MR. GOLOMB: Yeah, okay.

19 BY MR. GOLOMB:

20 Q Okay. Are you familiar with this
21 document that's in front of you, Exhibit 4?

22 A Yeah. Tom Locke showed it to me this
23 morning.

24 Q Okay. Do you know who prepared this

1 document?

2 A I actually don't.

3 Q Have you ever -- do you know what --
4 what information or documents was used to prepare
5 this?

6 A I assumed he consulted with our
7 accounting department to get the information.

8 Q Okay. So Mr. Locke would be
9 communicating with your accounting department
10 without your knowledge?

11 A Or it may have been with the knowledge
12 of Tom Myers, but it wasn't specifically through
13 me.

14 Q Okay. And you saw this for the first
15 time when?

16 A This morning.

17 Q Okay. And what does this document
18 purport --

19 A I know the -- the information was
20 covered in the interrogatories, and that they
21 had -- in order to respond to the interrogatories,
22 they had to put together this information.

23 Q Okay. Well, if this information was in
24 the answers to interrogatories, then why would we

1 need a separate document?

2 MR. LOCKE: I can answer it, because
3 your notice is broader than the interrogatories,
4 and we wanted to cover all the information. And
5 also based on some questions that were asked to
6 Ms. Loretz about non-talc-related contributions to
7 entities.

8 BY MR. GOLOMB:

9 Q And -- and so do you know what this
10 document purports to be?

11 A Yes.

12 Q What?

13 A Pay- -- any payments we would have
14 made -- that PCPC would have made to these
15 organizations.

16 Q Okay.

17 A And I think there -- there were only --
18 our accounting system only has records
19 electronically or whatever back to 2002.

20 Q Well, let -- let's go through this, and
21 that -- so does the PCPC have a relationship other
22 than a financial relationship with the National
23 Academy of Sciences?

24 A No, I don't even think we have a

1 financial relationship.

2 Q Well, that wasn't my question. My
3 question was --

4 A No, no relationship.

5 Q Okay. And does the -- if we assume for
6 the sake of discussion that these numbers are
7 accurate, it says with respect to these various
8 organizations that there have been no talc-related
9 payments, correct?

10 A Yes.

11 Q Okay. There -- there are some other
12 payments that have been made, and it says "i.e.,
13 charity and dues." Do you see that?

14 A Yes.

15 Q So as an example, \$90,700 of other
16 payments made to the American Cancer Society. Do
17 you know what those payments were made for?

18 A So it would be a mixture of things
19 because the American Cancer Society is a partner
20 with the Look Good Feel Better foundation on
21 producing -- on running the Look Good Feel Better
22 program. Also they had shared the proceeds of the
23 DreamBall.

24 So there may have been a reconciliation

1 of funds after the event, and there are different
2 things in our partnership agreement which, you
3 know, identifies who pays for certain printing
4 things, and I assume it was to reconcile accounts
5 per the agreement. There also may have been -- we
6 may have purchased seats at the DreamBall,
7 DreamBall tickets for certain staff members over
8 the years.

9 Q And the -- under the Consumer
10 Federation -- federal --

11 A So it should be Consumer Federation of
12 America.

13 Q Right. There were no talc-related
14 payments, but there were 367,000 and change of
15 other payments made between 2002 and 2018,
16 correct?

17 A Yes.

18 Q Okay. You would agree with me, would
19 you not, that you could have a relationship with
20 one or more of these companies that has nothing to
21 do with finances?

22 A Yes.

23 Q All right. And so do you know one way
24 or the other whether or not the PCPC has such a

1 relationship with the National Cancer Institute?

2 A I'm not aware of any, and it's never
3 come up.

4 Q All right. Who -- if such a
5 relationship existed, who would know that?

6 A I assume someone in the Science
7 department.

8 Q Okay. Linda Loretz, perhaps?

9 A Perhaps.

10 Q Okay. Because I would assume, correct
11 me if I'm wrong, that, as an example, the National
12 Cancer Institute may -- may be circulating
13 information through a study, through periodicals,
14 through their website that may have effect on some
15 of your members.

16 MR. LOCKE: Objection. Beyond the
17 scope. And form.

18 THE WITNESS: I -- it's possible. I
19 don't know.

20 BY MR. GOLOMB:

21 Q Okay. Let's go back to the cosmetic
22 industry review, the CIR.

23 We talked a lot about the administration
24 of the CIR, we talked a lot about the funding of

1 the CIR, the management of the CIR in terms of the
2 steering committee.

3 How are -- how are issues that get in
4 front of the CIR determined? Is it determined by
5 the -- by the -- by the steering committee?

6 MR. LOCKE: Objection. Beyond the
7 scope.

8 THE WITNESS: So I'm not sure what you
9 mean by issues. If you mean what ingredients are
10 they reviewing?

11 BY MR. GOLOMB:

12 Q Right.

13 A So there is a priority list that is
14 developed, and I think that's actually noted in
15 the procedures also. If not, it's explained on
16 their website. The priority list is based on
17 the -- how often an ingredient is used based on
18 the voluntary reporting program data on cosmetic
19 ingredient -- formulations and ingredients.

20 Q I know you answered this before, but
21 just refresh my memory, when was it that the CIR
22 was formulated?

23 A I think in 1976.

24 Q And why was it formulated?

1 A It was at a time where there was a lot
2 of legislation being considered in Congress that
3 would have mandatory, more stringent oversight of
4 the industry, and so we got together with Consumer
5 Federation of America and others and came up with
6 a -- with a voluntary reporting program, the idea
7 of international nomenclature, for uniform
8 nomenclature for cosmetic ingredients, and then a
9 review program for cosmetic ingredients that was
10 modeled on the FDA OTC drug review process.

11 Q Okay. And how -- how was it determined
12 what -- what ingredients will be reviewed by the
13 CIR?

14 MR. LOCKE: Objection. Form, beyond the
15 scope.

16 THE WITNESS: So that's where we go back
17 to the priority list based on indications of use
18 by what companies are filing with the FDA under
19 the voluntary program. Also there's a way for FDA
20 to petition and ask CIR to review ingredients, and
21 I think there's a consumer -- you know, an outside
22 group can come in and petition for review.

23 BY MR. GOLOMB:

24 Q Okay. And that petition could be either

1 accepted or denied, correct?

2 A Correct.

3 Q And so -- and ultimately those decisions
4 are made by the CIR steering committee.

5 A Right. And the steering committee
6 publishes the priority lists and everything is
7 transparent. And the meetings are open.

8 Q Okay. When you say "the meetings are
9 open," are there -- there are meetings to
10 determine what -- what ingredients will be
11 reviewed and what ingredients will not be
12 reviewed?

13 A So the actual meetings where they're
14 reviewing the literature and making the
15 determinations are open. When the priority list
16 is developed, I think it is presented at -- I
17 think they present the priority list for the year,
18 and I think that is subject to comment by anybody
19 in attendance at the meeting.

20 Q Okay. And are there minute -- minutes
21 of these meetings?

22 A Yes.

23 Q And how often do these minutes --
24 meetings occur?

1 A Four times a year.

2 Q And where are these meetings?

3 A Washington, D.C.

4 Q And who is specifically invited to these
5 meetings?

6 A They're open to the public, and they --
7 per the procedures, there is a notice put out and
8 posted on their website and circulated in the
9 trade.

10 Q Listed on the CIR website?

11 A Yes.

12 Q When is the next meeting?

13 A September 24th, I think.

14 Q Where?

15 A Washington -- they're held at hotels.

16 Q Okay. Where's that particular meeting
17 being held?

18 A I don't remember if it's the Madison
19 Hotel or not. That's where the last one was.

20 Q Okay. And since its inception, do you
21 have any idea of how many ingredients have been
22 reviewed by the CIR?

23 MR. LOCKE: Objection. Beyond the
24 scope.

1 THE WITNESS: Several thousand.

2 BY MR. GOLOMB:

3 Q Would you be surprised to know that the
4 number is -- is somewhere north of 5,000?

5 A No, I --

6 Q And out of those 5,000 or so ingredients
7 that have been reviewed, would you surprise -- be
8 surprised to know that 13 of them have been
9 concluded to be unsafe?

10 MR. LOCKE: Objection to form and beyond
11 the scope.

12 THE WITNESS: Yeah, that sounds
13 approximately right.

14 BY MR. GOLOMB:

15 Q Okay. So the -- the CIR, which is
16 maintained by the PCPC, has found that less than
17 .0025 percent of the ingredients that it has
18 reviewed to be unsafe for consumer use; is that
19 correct?

20 MR. LOCKE: Objection to form and beyond
21 the scope.

22 THE WITNESS: Well, I haven't done the
23 math.

24 BY MR. GOLOMB:

1 Q Okay. If I told you I have done the
2 math, would you trust me?

3 MR. LOCKE: Objection to the form.

4 (Laughter.)

5 BY MR. GOLOMB:

6 Q Let's take a look at some documents.

7 Now, you told us that in the -- that the
8 last -- well, first of all -- strike that.

9 You -- and this is a little confusing to
10 me, so maybe you can help me out. You told us on
11 the one hand that over the last ten years or so
12 that the PCPC and its members are transitioning
13 from this desire to be self-regulatory to no
14 longer being self-regulatory.

15 In the simplest terms, is that what you
16 told me?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 THE WITNESS: So I think that's a little
20 bit of a mischaracter-- -- characterization.

21 I think the -- the movement is towards a
22 little more mandatory regulation, but it's based
23 on consumer research that consumers are looking
24 for that, have that expectation.

1 BY MR. GOLOMB:

2 Q Okay. Well, I'm wondering, were you --
3 since -- I don't know if you -- if you know this,
4 but because you told us that you didn't review --
5 sorry, you did not review the website in
6 preparation for your deposition.

7 So I wonder if you agree or disagree
8 with the statement that says: "The CTFA strongly
9 opposes the attempt to remove the self-regulatory
10 status of the cosmetic industry."

11 Is that an accurate statement?

12 A We wouldn't have used --

13 MR. LOCKE: Objection. Form and beyond
14 the scope.

15 Go ahead.

16 THE WITNESS: If we're saying CTFA, then
17 it's a very outdated document because the name
18 changed.

19 BY MR. GOLOMB:

20 Q When did the name change from CTFA
21 change to -- to PCPC?

22 A January 1, 2008.

23 Q Okay. So it's at the time -- around the
24 time that the CTFA changed its name to the PCPC

1 was around the time that the -- they were
2 transitioning from this group that -- that
3 strongly opposed anything other than a -- a
4 self-regulatory status, that's a quote, of the
5 cosmetic industry to being more of a mandatory
6 regulation?

7 A I would say that was --

8 MR. LOCKE: Hang on.

9 Objection to form, beyond the scope.

10 THE WITNESS: That was part of it. It
11 was part of the same consumer -- the reason we
12 changed the name was also based on consumer
13 research.

14 BY MR. GOLOMB:

15 Q Consumer research done by who?

16 A Different outside groups, not any of the
17 groups involved with this.

18 Q And you're familiar with Proposition 65?

19 A Yes.

20 Q What is Proposition 65?

21 MR. LOCKE: Objection. Beyond the
22 scope.

23 THE WITNESS: It's a -- it's a
24 California ballot initiative that was passed that

1 requires warning labels on various consumer
2 products that are -- have any association with the
3 possibility of being a carcinogen.

4 BY MR. GOLOMB:

5 Q Okay. And you're aware, are you not,
6 that when that was voted on by the voters of
7 California back in 1986 that the PCPC and its
8 members spent over \$600,000 to defeat that bill,
9 correct?

10 MR. LOCKE: Objection to form, beyond
11 the scope.

12 THE WITNESS: I -- I know we opposed it.
13 I -- I don't know how much we spent on that.

14 BY MR. GOLOMB:

15 Q Okay. So then, am I to then understand
16 your testimony here today that if that same
17 initiative was -- was seeking passage, that the
18 PCPC position with respect to Proposition 65 would
19 be different?

20 MR. LOCKE: Objection to form, beyond
21 the scope.

22 THE WITNESS: No.

23 BY MR. GOLOMB:

24 Q It would be the same?

1 A Yeah.

2 Q They would want defeat of that bill?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 BY MR. GOLOMB:

6 Q Correct?

7 A Probably.

8 Q Okay.

9 MR. GOLOMB: What are we -- around 5?
10 Exhibit 5.

11 (Pollak Exhibit No. 5 was marked
12 for identification.)

13 BY MR. GOLOMB:

14 Q This is a PCPC document 52417, which
15 we've marked as Exhibit 5, and it is a CTFA
16 Mission Statement. And there's a -- it's a
17 composite document that we will look at some of
18 the pages of.

19 Have you seen this before?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: I'm sure I have, but
22 again, it's at least ten years old.

23 BY MR. GOLOMB:

24 Q Do you know when this document was

1 created?

2 A Not specifically, but I would imagine
3 between 2005 and 2007.

4 Q Okay. And certainly before that time,
5 the issue of talc and ovarian cancer was -- was an
6 issue of concern for the CFTA, correct?

7 A For CTFA?

8 Q CTFA.

9 A But it was one of many.

10 Q Well, I understand, but --

11 A Yeah.

12 Q -- it was -- I mean, in fact, sunscreen
13 was another one at that time that was an issue --
14 it was one of many, but it was an issue to --

15 A Mm-hmm.

16 Q -- its members, particularly Imerys and
17 J&J.

18 A Mm-hmm.

19 MR. DONATH: Objection.

20 MR. LOCKE: You need to say --

21 THE WITNESS: Yes.

22 BY MR. GOLOMB:

23 Q Do you know who Dr. Alfred Wehner is?

24 A No.

1 Q Do you know who the Biomedical
2 Environmental Consultants are?

3 A No.

4 Q Okay. So you -- you haven't seen any of
5 the communications between the CTFA and -- well,
6 you know who Stephens -- strike that.

7 You know who Stephen Gettings is, right?

8 A Yes.

9 Q So you haven't seen any of the documents
10 and the communications between Stephen Gettings
11 and Dr. Wehner beginning in 1993?

12 A It's possible I did in preparation for
13 the last deposition. I looked at a lot more
14 documents. But in -- since it's been almost three
15 years, I can't recall specifically which documents
16 I looked at.

17 Q Okay. And so you're unaware of the
18 retention of Dr. Wetting -- Dr. Wehner by
19 Dr. Gettings to deal with the talc/ovarian cancer
20 issue?

21 MR. LOCKE: Objection to form and beyond
22 the scope.

23 THE WITNESS: I'm familiar with the
24 name. I know the name has come up, but more than

1 that, I can't be sure.

2 BY MR. GOLOMB:

3 Q Okay. And when you say you know that
4 it's come up, how do you know that?

5 A The name is familiar from the earlier
6 preparation, but as far as what his role was, I
7 don't recall exactly.

8 Q Okay. And do you know who the
9 International Society of Regulatory Toxicology and
10 Pharmacology is?

11 A In a very general sense, yes.

12 Q What's -- what's your understanding as
13 to who they are?

14 A Well, our -- certain members of the
15 Science department I know participate in meetings
16 of different professional societies and outside
17 organizations involved in toxicology, and they may
18 have gone to meetings of this group.

19 Q Okay. And are -- are you aware that
20 with the coordination again of Stephen Gettings --
21 who was the director of toxicology at one time,
22 correct?

23 A Yes, sounds right.

24 Q When -- when did he leave?

1 A I think he left in the late '90s.

2 Q Okay. You're aware, are you not, that
3 with the coordination of Dr. Gettings at the ISRTP
4 held meetings looking at, -- as far back as 1994,
5 looking at the association of talc and ovarian
6 cancer?

7 MR. LOCKE: Objection to form and beyond
8 the scope.

9 BY MR. GOLOMB:

10 Q Were you aware of that?

11 A Not specifically.

12 Q Okay. And were you aware that the CTFA
13 contributed \$20,000 towards that, quote/unquote,
14 workshop?

15 A Not -- not specifically.

16 Q So I asked you earlier about the
17 Weinberg Group.

18 A Mm-hmm.

19 Q I assume from your answers you either
20 haven't or don't recall reviewing the Weinberg
21 Group report.

22 A Again, it's so long ago, it's possible I
23 read it at the time. I -- I can't be sure.

24 Q Okay. Well, the report was authored in

1 October of 2000, weeks before the NTP
2 presentation. Does that help refresh your
3 recollection at all?

4 A Not really. I mean...

5 MR. GOLOMB: Exhibit 12.

6 (Pollak Exhibit No. 12 was marked
7 for identification.)

8 BY MR. GOLOMB:

9 Q This is Exhibit 12, and just to put this
10 into context, this is the page that follows --

11 A Right.

12 Q -- Exhibit 11.

13 A Mm-hmm.

14 Q Which I asked you some questions about
15 before, the organization of the CIR.

16 A Mm-hmm.

17 Q And if we go to section 12 on page 5.

18 A Mm-hmm. Right. So -- so there would be
19 one monitor --

20 Q Let me just -- let me ask you a
21 question.

22 Under Section 12, "Director. (a) the
23 director shall be appointed by the chair of the
24 steering committee." Correct?

1 A So as -- so it's the current title is
2 executive director.

3 Q Okay.

4 A And, yes, the executive director is
5 formally appointed by the chair of the steering
6 committee.

7 Q And the -- in this case the director as
8 well as the chair of the steering committee are
9 both PCPC employees.

10 A Yes.

11 Q Okay. And then under (b): "The
12 director" -- again, who is a PCPC employee --
13 "shall hire and direct the activities of the CIR
14 staff."

15 So you've got the executives of the PCPC
16 are directing the activities of the CIR staff --

17 A No, no.

18 Q -- in order to implement these
19 procedures effectively and efficiently, correct?

20 A No.

21 Q Is that not what it says?

22 A No, it's the exec- --

23 Q Did I read that incorrectly?

24 A Remember it's the executive director who

1 is the CIR employee. The executive director of
2 CIR is directing the activities of the CIR staff.

3 Q Okay. Appointed by the chair of the
4 steering committee, which is the PCPC executive.

5 A Yes.

6 Q Okay. So -- and the chairman of the
7 steering committee -- under (b)(2), "The chairman
8 of the steering committee shall periodically
9 review CIR expenditures." Correct?

10 A Yes.

11 Q So -- and these are a number of the
12 expenditures that we talked about before, like
13 salaries, office supplies, office space --

14 A Mm-hmm.

15 Q -- travel to meetings --

16 A Yes.

17 Q -- all of those things that we talked
18 about previously.

19 A Yes.

20 Q They're all directed by the PCPC
21 ultimately, correct?

22 MR. LOCKE: Objection to form.

23 THE WITNESS: At a minimum, reviewed,
24 yes. I mean they have a budget and every

1 department is --

2 BY MR. GOLOMB:

3 Q Right. And the --

4 A -- supposed to keep within their budget.

5 Q And the executives of the PCPC approve
6 that budget and can approve overexpenditures or
7 not at its sole discretion.

8 A Yes.

9 Q And then as we go further down under
10 (a)(3), "All CIR contracts and capital
11 expenditures shall be reviewed and approved by the
12 chairman of the steering committee prior to
13 execution."

14 So when the CIR enters into a contract,
15 like they did with Dr. Josh Muscat or they did
16 with Dr. Alfred Wehner or like they did with
17 Dr. Huncharek, all those contracts have to be
18 approved by the chairman of the steering committee
19 who was an executive at the PCPC, correct?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: Yes, we would have to
22 approve the contracts. I'm not familiar with
23 those specific contracts, though.

24 BY MR. GOLOMB:

1 Q Understood. But if -- if I told you
2 that those are various scientists that were hired
3 for the purposes of defending the -- the PCPC and
4 its interested members, any contract with those
5 people would first have to be approved by the
6 PCPC.

7 MR. LOCKE: Objection. Are you talking
8 about CIR or PCPC?

9 MR. GOLOMB: CIR.

10 THE WITNESS: So, no, that wouldn't be
11 the purpose of the CIR contract.

12 BY MR. GOLOMB:

13 Q Okay. Have you seen the -- the CIR
14 study on the association of talc and ovarian
15 cancer?

16 MR. LOCKE: Objection. Beyond the
17 scope.

18 THE WITNESS: I -- I don't recall.
19 Again, that's possible in preparation for the last
20 deposition I did see it, but I don't know.

21 BY MR. GOLOMB:

22 Q Okay. Do you know one way or the other
23 as to whether or not one exists?

24 A Yeah. No, I know they reviewed it,

1 so...

2 Q And you know that based on everything
3 that we've talked about this morning, based on
4 these two documents, 11 and 12, if there was such
5 a -- if there was such a study, and it was paid
6 for, it would have to be -- it would have to first
7 be approved by the chairman of the steering
8 committee that happens to be an executive with the
9 PCPC, correct?

10 MR. DONATH: Objection.

11 MR. LOCKE: Objection to form.

12 THE WITNESS: Right. But the purpose of
13 the contract would be to develop additional data
14 to meet the request of the expert panel members.
15 It isn't to defend particular ingredients. It's
16 to try to develop more information.

17 BY MR. GOLOMB:

18 Q And -- but this CIR contract would first
19 have to be approved by an executive of the PCPC.

20 A Yes.

21 Q And that executive of the PCPC gets
22 his -- his -- his salary from the operating
23 expenses of the PCPC. Correct?

24 A Yes.

1 Q And the PCPC operating expenses comes
2 from the industry members, like J&J, like Imerys.

3 A Yes.

4 Q Right. And do you know one way or the
5 other as to whether or not before -- after such a
6 contract is entered into and after a report is
7 issued under this contract, whether or not those
8 members who are paying dues to the PCPC, who are
9 then paying for the research that's done by the
10 CIR, whether or not they have an opportunity to
11 review those studies before they get circulated?

12 MR. LOCKE: Objection.

13 MR. DONATH: Objection. Beyond the
14 scope.

15 MR. LOCKE: And to form.

16 THE WITNESS: And they -- and they
17 wouldn't have an opportunity.

18 BY MR. GOLOMB:

19 Q They wouldn't?

20 A No.

21 Q And you know that how?

22 A If the CIR is doing a contract for a
23 study, it would go back to the CIR expert panel
24 members. It wouldn't be going out to the members

1 as part of the process.

2 Q So you would --

3 A If it was -- and if it was being made
4 available publicly, it would be made available to
5 everyone.

6 Q Okay. So you would agree with me that
7 had the -- the CIR before publishing their study
8 on the association between talc and ovarian
9 cancer, if they had circulated a draft report or
10 more than one draft report to its members, like
11 Johnson & Johnson, like Imerys, that that would be
12 an inappropriate thing to do?

13 MR. LOCKE: Objection.

14 MR. DONATH: Objection. This is all
15 beyond the scope of the notice.

16 THE WITNESS: Well --

17 MR. LOCKE: Wait. Objection. Beyond
18 the scope and to form.

19 THE WITNESS: The members are not
20 members of the CIR. It's a separate thing.

21 BY MR. GOLOMB:

22 Q Well, I understand that.

23 But would you agree with me that had the
24 CIR contracted out to do a study, like they did in

1 this case, to look at the association between talc
2 and ovarian cancer -- one of the things that you
3 told me last time and that you told me again today
4 is it is important for the CIR to be independent.
5 Correct?

6 A Yes.

7 MR. LOCKE: Objection. It's compound,
8 assumes facts not in evidence, and incorrect. And
9 beyond the scope.

10 MR. GOLOMB: Anything else you want to
11 object to?

12 MR. LOCKE: Well, your -- the
13 fundamental premise of your whole argument is --

14 MR. GOLOMB: No, no, no, don't --

15 MR. LOCKE: You asked --

16 MR. GOLOMB: No, no.

17 MR. LOCKE: You asked me if there is
18 anything else.

19 MR. GOLOMB: No, no, no. No speaking
20 objections. You made your objection.

21 MR. LOCKE: But you asked me.

22 MR. GOLOMB: No -- no, I didn't really.

23 MR. LOCKE: You said if there was
24 anything else. I'm explaining to you.

1 MR. GOLOMB: Yeah. And I appreciate
2 that.

3 BY MR. GOLOMB:

4 Q You -- you have made a point, as have
5 others, on the last deposition and this deposition
6 that -- that it's important for the CIR to
7 maintain its independence, correct?

8 A Yes.

9 Q Okay. And would you -- you would agree
10 with me, would you not, that in maintaining one's
11 independence, credibility is very important?
12 Would you agree with that?

13 A Yes.

14 Q And would you agree with me that in a
15 case where the CIR has -- is contracting out to,
16 in this case, Dr. Huncharek to write a report,
17 that you lose credibility if you're now -- if he
18 is providing a draft back to not only the PCPC but
19 the members of the Talc Interested Party Task
20 Force.

21 MR. LOCKE: Objection to form --

22 MR. DONATH: Objection to form, beyond
23 the scope of the notice.

24 MR. LOCKE: -- and beyond the scope.

1 BY MR. GOLOMB:

2 Q Would you agree?

3 A I have no knowledge of what really the
4 study did or what the protocols were and who --
5 who it was shared with.

6 Q Well, my -- I'm sorry, to interrupt you.
7 I want to wait and make sure you've answered your
8 question.

9 You would agree with me under my
10 hypothetical, if that was done, you've got a
11 credibility problem.

12 MR. DONATH: Objection.

13 MR. LOCKE: Objection to form and beyond
14 the scope.

15 THE WITNESS: I think it's beyond my
16 area of expertise. I don't know what the normal
17 protocol is in these studies.

18 BY MR. GOLOMB:

19 Q Okay. Well, you were the one before who
20 said that they didn't do that. How do you know
21 that they didn't do that?

22 MR. LOCKE: Objection. Didn't do what?

23 BY MR. GOLOMB:

24 Q Didn't provide the draft reports to not

1 only the PCPC but to -- to members of the
2 interested party task force.

3 MR. LOCKE: Objection to form, beyond
4 the scope.

5 BY MR. GOLOMB:

6 Q You were the one who said it.

7 A I --

8 MR. DONATH: Objection.

9 MR. LOCKE: Again, same objection.

10 THE WITNESS: I -- you know, I don't
11 know -- I would think that that would not be under
12 the procedures the way it would be handled.

13 MR. LOCKE: Can -- can we take a break
14 to see if lunch is here?

15 MR. GOLOMB: Sure. You know, if you
16 want to take a five-minute break before doing
17 that, and don't move, we may not need a break.

18 MR. LOCKE: Okay. Can I just -- can the
19 witness -- can we just take a break so the witness
20 can go out and go to the bathroom and come back,
21 and the rest of us just stay here?

22 MR. GOLOMB: Sure.

23 THE VIDEOGRAPHER: The time is
24 12:12 p.m., and we're going off the record.

1 MR. LOCKE: Let me wait until the
2 witness leaves and then suggest one thing.

3 I don't want to in any way influence
4 what the witness is saying or not. You can ask
5 all your questions. There is no document that
6 indicates CIR ever contracted with Huncharek,
7 Muscat or any other expert.

8 If you've got it, that's great, show it
9 to the witness, but I don't think any of us have
10 seen it, and if you want to confer with your
11 co-counsel, I suspect they will tell you the same
12 thing.

13 MR. GOLOMB: Okay. Anything else?

14 MR. LOCKE: No, I'm just --

15 MR. GOLOMB: Thanks.

16 (Recess.)

17 THE VIDEOGRAPHER: The time is
18 12:32 p.m. We're back on the record.

19 MR. GOLOMB: First of all, I just want
20 to -- I just want to -- I did check with my
21 colleagues, and, Mr. Locke, you're correct, I
22 misstated the author of the CIR report. It's
23 Monice Fiume.

24 BY MR. GOLOMB:

1 Q Is that your understanding?

2 A I have no -- no knowledge of it.

3 Q Okay. I just don't remember, is she
4 still with the --

5 A Yeah, she is.

6 Q Okay. But in any event, if she's the
7 author of the study, you would agree that it would
8 be inappropriate to provide that study to both the
9 PCPC and PCPC members to edit and review for
10 comment before it went and got -- it actually got
11 published?

12 MR. LOCKE: Objection to form and beyond
13 the scope.

14 THE WITNESS: I think there's a
15 possibility that the -- somebody looked at it to
16 make sure it was what the panel was expecting or
17 that the language, you know, was concise and
18 understandable, but I -- I really don't know.

19 BY MR. GOLOMB:

20 Q Okay. Before when we were -- if you
21 remember, I was asking you some questions about
22 the -- the Dezenhall group and --

23 A Yes.

24 Q -- their crisis management work that

1 they were doing at around the time of the NTP, and
2 you had mentioned that -- that the PCPC had
3 retained Dezenhall on a -- on a previous occasion
4 on some fragrance issues.

5 Do you remember what you -- when you
6 told me?

7 A Yes, I do.

8 Q What were you referring to?

9 A Multiple chemical sensitivity. There
10 was a whole campaign against the industry by
11 people who claimed when they were exposed to other
12 people wearing fragrances, they experienced
13 multiple chemical sensitivity.

14 Q And -- and what was Dezenhall's role?

15 A So we worked with them on, I guess,
16 communications materials. I -- I don't recall if
17 there was any research done or how it was more
18 media related.

19 Q Okay. By the way, you had mentioned to
20 us earlier that the -- I had asked you when the
21 next board meeting was of the -- the
22 September 24th board meeting was --

23 A No, that's the CIR expert panel meeting.

24 Q Yeah.

1 A The board meeting is October 3rd.

2 Q Okay. But you told us that the CIR
3 meeting was open to the public.

4 A Correct.

5 Q Right. And you also told us that it
6 would be on the CIR website.

7 A It should be. They post the meeting
8 announcements.

9 Q Okay. We -- we checked the CIR website
10 during the break, and it's not on there. So do
11 you know when it will be posted?

12 MR. LOCKE: Objection. Form.

13 THE WITNESS: I don't.

14 BY MR. GOLOMB:

15 Q Do you know what the agenda is for that
16 meeting?

17 A No.

18 Q Do you know whether or not -- how -- how
19 is the agenda for a CIR meeting like that
20 selected --

21 MR. LOCKE: Object --

22 BY MR. GOLOMB:

23 Q -- and finalized?

24 MR. LOCKE: Objection. Beyond the

1 scope.

2 You can answer.

3 THE WITNESS: I think Linda Loretz is in
4 a better position to -- to discuss that.

5 BY MR. GOLOMB:

6 Q Okay. But you don't know -- sitting
7 here today, you don't know generally what the
8 issues are and specifically whether or not --

9 A Well, I know --

10 Q Let me just finish the question.
11 -- and specifically whether or not the
12 association of talc and ovarian cancer is on that
13 agenda?

14 A I -- the agenda would be the tentative
15 final and final reports that are ready for
16 presentation to the expert panel, and I'm not
17 aware of anything involving talc coming up.

18 Q Okay. Let me just ask you, is -- is
19 Whitaker Clark Daniels, are they a member of the
20 PCPC?

21 A I think so. I mean they have been in
22 the past.

23 Q Brenntag Specialties?

24 A I'm not familiar with them.

1 Q Cyprus Amax?

2 A I -- the -- Cyprus Minerals I'm familiar
3 with. I assume it's the same company.

4 Q Rio Tinto?

5 A I don't know.

6 Q Do you know who Crowell & Moring is?

7 A Yes, a law firm.

8 Q Okay. Are they a member?

9 A I don't think so. We do have a few law
10 firms who are members for marketing purposes.

11 Q What do you mean "for marketing
12 purposes"?

13 A They made a decision to be a sponsor at
14 a legal conference, and to, you know, basically
15 to -- business development, so they joined the
16 association as an associate member.

17 Q Okay. But you don't know one way or the
18 other whether or not Crowell & Moring is one of
19 them?

20 A They may be. I know there are eight to
21 ten law firms who are members, and I -- I'm just
22 not familiar with them, who they all are.

23 Q You have the revenue chart for the task
24 force?

1 A Mm-hmm.

2 Q Yes? You have to --

3 A No. 3 -- Exhibit No. 3?

4 Q Yeah. The -- on that -- on that
5 sheet -- now, my understanding is that that sheet
6 was prepared shortly before your 2016 deposition.
7 And if that's correct, does that mean that there
8 have not been any contributions to the interested
9 party task force since 2009?

10 A I would presume so. That's what it
11 indicates.

12 Q Okay. Well, how can we -- how can we
13 find out for sure whether or not -- I mean I --
14 I'm assuming that also because that document was
15 prepared in 2016, and I would assume, you correct
16 me if I'm wrong, that if contributions were made
17 in 2010, 2011 through 2016, that it would be on
18 that sheet.

19 A I agree.

20 Q Okay. So if we -- if we assume it's
21 true that no funds have been received from the
22 members of the interested party task force since
23 2009, and we know that the CIR report came well
24 after 2009, how was it paid for?

1 A So the -- I think there are two ways
2 that it can be paid for. CIR has some money in
3 their budget for reports or research that are
4 requested by the expert panel members. And,
5 again, I don't know the specifics of this -- of
6 this particular report that you're talking about,
7 and there have been other instances where there --
8 the panel wants more information, and some company
9 agree -- some companies agree to fund it.

10 Q So --

11 A But I -- again, this is just general. I
12 have no idea what applies in this.

13 Q Right. So, hypothetically, it may be
14 the case that not only did member groups have an
15 opportunity to comment and edit on the report but
16 also pay for it?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 THE WITNESS: Possibly. I don't know
20 how this was set up.

21 BY MR. GOLOMB:

22 Q Do you know who the Health Research
23 Group is?

24 A No.

1 Q Do you know who the --

2 A So is --

3 Q -- Consumer Research Group is?

4 A Excuse me. So is this on -- should I
5 look at this list?

6 Q Sure. If that helps.

7 A Yeah. No, they're off.

8 Q Are they on there?

9 A No.

10 Q Do you know who the Consumer Research
11 Group is?

12 A No.

13 MR. GOLOMB: I don't have any further
14 questions.

15 Can I see the --

16 THE WITNESS: Exhibit 4.

17 BY MR. GOLOMB:

18 Q Yeah, this is Exhibit 4 we're looking
19 at, and you've got the -- it says "Consumer
20 Federal," but we agree it's the Consumer
21 Federation --

22 A Right.

23 Q -- of America, right?

24 And they made payments of \$367,000

1 between 2002 and 2018. I guess my question is
2 why?

3 A So I would assume it's for --

4 MR. LOCKE: Let me object to form. I
5 think that shows payments that PCPC made to these
6 other entities.

7 MR. GOLOMB: You're correct.

8 BY MR. GOLOMB:

9 Q Why?

10 A So -- I think there are two -- two
11 areas. Number one, the Consumer Federation of
12 America has an annual fundraising dinner and they
13 feature prominent speakers, and I think for years
14 we've been buying a table at the event. It's
15 probably five or 10,000.

16 Plus the -- the liaison from Consumer
17 Federation of America is entitled -- the liaison
18 to the CIR expert panel is entitled to
19 reimbursement for his or her preparation time, and
20 the time that he or she spends at the expert panel
21 meeting at the same rate the other expert
22 panels -- expert panel members are entitled to
23 reimbursement. And I think in this case they --
24 the individual can't have the check made out to

1 them. They have it made out to Consumer
2 Federation of America.

3 Q You also mentioned earlier in the -- in
4 the deposition, I was asking you about the -- we
5 were talking about this transition from the desire
6 to be self-regulatory to having some mandatory
7 regulation to be consistent internationally,
8 correct?

9 Do you remember that --

10 A Mm-hmm.

11 Q -- those series of questions?

12 A Yes.

13 Q You mentioned in the course of one of
14 your answers that you had hired some outside
15 consumer research groups to help you through that
16 transition. Who did you use?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 You can answer.

20 THE WITNESS: Frank Luntz and Michael
21 Maslansky.

22 BY MR. GOLOMB:

23 Q Frank Luntz. And what did you use Frank
24 Luntz to do?

1 MR. LOCKE: Same objection.

2 THE WITNESS: And again, some of this
3 may have been subcontracted. You know, before we
4 changed the name, they did, you know, I guess
5 online surveys, possibly focus groups on how
6 different names -- the, you know, favorability
7 ratings by different brackets of consumers and
8 other stakeholders, and probably on some of the --
9 you know, consumer awareness of different issues
10 in the cosmetic media space.

11 BY MR. GOLOMB:

12 Q And was it based on that research, at
13 least in part, why the name was changed from the
14 CTFA to PCPC?

15 A Partially, yes.

16 Q Okay. And if -- if somebody, you know,
17 at a cocktail party asked you and said, Why did
18 the CTFA change their name to PCPC -- I understand
19 there are some boring cocktail parties in D.C.
20 where they would have such conversations -- what
21 would your answer be, why?

22 A Mainly because the term "toiletry" was
23 archaic, and people didn't really know what it
24 meant anymore, and we had to get away from using

1 that.

2 Q Okay. And did you -- were there any
3 other consumer research groups that you -- outside
4 consumer research groups that you used?

5 A No.

6 Q For any other issues?

7 A There may have been at the time, but
8 I -- I wouldn't have been involved in the name
9 change.

10 MR. GOLOMB: Okay. I don't have
11 anything further, unless my colleagues have
12 something. Michelle always has something.

13 (Counsel conferring.)

14 MR. GOLOMB: We'll only be another hour
15 or so.

16 (Laughter.)

17 MR. GOLOMB: Can I see the
18 organizational chart again?

19 BY MR. GOLOMB:

20 Q First of all, to your knowledge, whether
21 it was Frank Luntz or some other consumer research
22 group, were there any other -- were there any
23 outside consumer research groups that was hired by
24 PCPC to deal with any talc issue that you're aware

1 of?

2 MR. LOCKE: Objection. Beyond the
3 scope.

4 THE WITNESS: So, again, are you
5 referring to the time of the name change or --
6 BY MR. GOLOMB:

7 Q No, at any time. We -- we talked
8 about --

9 A I don't think -- I don't think a public
10 affairs firm -- you know, I know that
11 Nichols-Dezenhall made a pitch, but I don't think
12 we did anything with it. And other than that, I'm
13 not aware of any other firm.

14 Q Okay. So let me just be clear about
15 that, because the -- you used the term "consumer
16 research group" when we were talking much earlier
17 about the name change, and then I talked -- I just
18 asked you about Frank Luntz. At least that was
19 part of your answer.

20 My -- my -- so using your terminology of
21 "consumer research group," do you consider
22 Nichols-Dezenhall a consumer research group?

23 A Not really. I mean Nichols-Dezenhall is
24 much more focused on media relations.

1 Q Right.

2 A What I meant by consume- -- a group that
3 does research on consumer attitudes.

4 Q Okay. And my question to you is, has
5 the PCPC, to your knowledge, hired any such
6 consumer research group to deal with talc issues?

7 MR. LOCKE: Objection. Beyond the
8 scope.

9 THE WITNESS: Again, not that I'm aware
10 of.

11 BY MR. GOLOMB:

12 Q Okay. And my last question is related
13 to Monice -- how do you pronounce her last name?

14 A Fiume.

15 Q Is she still -- on the chart it has her
16 as scientific analyst.

17 A So she got a promotion, and I -- whether
18 it's senior scientific or deputy director,
19 she's -- she's at a higher level than on that
20 organization chart.

21 Q Okay. And have her duties and
22 responsibilities changed or just her title?

23 A So the reason she got the promotion is
24 because she has a fair amount of responsibility of

1 reviewing the draft reports that the other science
2 writers prepare there, as well as doing her own
3 reports.

4 Q And when did her promotion take place?

5 A Last year.

6 Q When last year?

7 A Probably -- approximately a year ago,
8 sometime during the summer, when the previous
9 executive director Lillian Gill retired, and we
10 made the determination to promote Bart, and then
11 we did promote Monice also.

12 Q Okay. And did somebody do a performance
13 review of Monice?

14 A I assume that Bart did.

15 Q Okay. And do you know whether or not
16 her -- her promotion had anything to do with the
17 publication of the CIR report?

18 A Of the specific report or --

19 Q Yeah.

20 A No. I mean, in general, she would --
21 you know, the -- the staff writers have reports
22 that are part of the normal processes. There are
23 different layers of review and editing to make
24 sure the -- the language is accurate and precise.

1 Q Would it -- would a -- a performance
2 evaluation -- the last performance evaluation of
3 an employee before they were promoted tell us
4 anything about the reasons why they were promoted?

5 A Possibly.

6 Q Okay. And so if -- if Monice was
7 promoted because of her involvement in a -- in a
8 CIR report concerning talc and the association
9 with ovarian cancer, would it be reasonable to
10 assume that that may be part of her performance
11 review?

12 A I would be very surprised that one
13 particular report would be cited that way.

14 Q Has there been any additional research,
15 whether it's CIR or retained by somebody that PCPC
16 hired, on the association of talc and ovarian
17 cancer since the CIR report, to your knowledge?

18 MR. LOCKE: Objection. Beyond the
19 scope.

20 THE WITNESS: Not to my knowledge.

21 MR. GOLOMB: Okay. I have no further
22 questions. You should -- you should probably run
23 before somebody starts handing me more notes.

24 MR. LOCKE: Does anyone else have any

1 questions?

2 No questions.

3 THE VIDEOGRAPHER: Okay. The time is
4 12:51 p.m., August 29th, 2018. We are going off
5 the record, completing the videotaped deposition.

6 (Whereupon, the deposition of
7 MARK POLLAK was concluded
8 at 12:51 p.m.)

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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

2 The undersigned Certified Shorthand Reporter
3 does hereby certify:

4 That the foregoing proceeding was taken before
5 me at the time and place therein set forth, at
6 which time the witness was duly sworn; That the
7 testimony of the witness and all objections made
8 at the time of the examination were recorded
9 stenographically by me and were thereafter
10 transcribed, said transcript being a true and
11 correct copy of my shorthand notes thereof; That
12 the dismantling of the original transcript will
13 void the reporter's certificate.

14 In witness thereof, I have subscribed my name
15 this date: August 30, 2018.

16

17

18 _____
LESLIE A. TODD, CSR, RPR

19 Certificate No. 5129

20 (The foregoing certification of
21 this transcript does not apply to any
22 reproduction of the same by any means,
23 unless under the direct control and/or
24 supervision of the certifying reporter.)

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2 Please read your deposition over carefully and
3 make any necessary corrections. You should state
4 the reason in the appropriate space on the errata
5 sheet for any corrections that are made. After
6 doing so, please sign the errata sheet and date
7 it.

8 You are signing same subject to the changes
9 you have noted on the errata sheet, which will be
10 attached to your deposition. It is imperative
11 that you return the original errata sheet to the
12 deposing attorney within thirty (30) days of
13 receipt of the deposition transcript by you. If
14 you fail to do so, the deposition transcript may
15 be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby
certify that I have read the foregoing pages, and
that the same is a correct transcription of the
answers given by me to the questions therein
propounded, except for the corrections or changes
in form or substance, if any, noted in the
attached Errata Sheet.

MARK POLLAK DATE

Subscribed and sworn to
before me this
_____ day of _____, 20____.
My commission expires: _____

Notary Public

Exhibit 120

Linda Loretz, Ph.D.

Page 379

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

-----x

IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)

-----x

V O L U M E I I

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT
PERSONAL CARE PRODUCTS COUNCIL
by and through its Designated Representative,

LINDA LORETZ, Ph.D.

WASHINGTON, D.C.

MONDAY, OCTOBER 1, 2018

9:09 A.M.

Reported by: Leslie A. Todd

Linda Loretz, Ph.D.

<p style="text-align: right;">Page 380</p> <p>1 Deposition of LINDA LORETZ, Ph.D., held at the 2 offices of: 3 4 5 SEYFARTH SHAW LLP 6 975 F Street, N.W. 7 Washington, DC 20004 8 9 10 11 12 Pursuant to notice, before Leslie Anne Todd, 13 Court Reporter and Notary Public in and for the 14 District of Columbia, who officiated in 15 administering the oath to the witness. 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 382</p> <p>1 APPEARANCES (CONTINUED): 2 3 MICHELLE A. PARFITT, ESQUIRE 4 ASHCRAFT & GEREL, LLP 5 4900 Seminary Road, Suite 650 6 Alexandria, Virginia 22311 7 (703) 997-1774 8 9 NICHOLAS J. KOHRS, ESQUIRE 10 LUNDY, LUNDY, SOILEAU & SOUTH, LLP 11 501 Broad Street 12 Lake Charles, Louisiana 70601 13 (337) 439-0707 14 15 ON BEHALF OF PCPC AND THE WITNESS: 16 THOMAS T. LOCKE, ESQUIRE 17 SEYFARTH SHAW LLP 18 975 F Street, NW 19 Washington, DC 20004 20 (202) 463-2400 21 22 23 24 25</p>
<p style="text-align: right;">Page 381</p> <p>1 A P P E A R A N C E S 2 3 ON BEHALF OF THE PLAINTIFFS: 4 CHRISTOPHER V. TISI, ESQUIRE 5 LEVIN PAPANTONIO THOMAS MITCHELL 6 RAFFERTY & PROCTOR, PA 7 316 S. Baylen Street, Suite 600 8 Pensacola, Florida 32502 9 (850) 436-6250 10 11 RICHARD M. GOLOMB, ESQUIRE 12 BENJAMIN ISSER, ESQUIRE 13 GOLOMB & HONIK, P.C. 14 1835 Market Street, Suite 2900 15 Philadelphia, Pennsylvania 19103 16 (215) 985-9177 17 18 TED MEADOWS, ESQUIRE 19 P. LEIGH O'DELL, ESQUIRE 20 RYAN BEATTIE, ESQUIRE 21 BEASLEY, ALLEN, CROW, METHVIN, PORTIS & 22 MILES, P.C. 23 218 Commerce Street 24 Montgomery, Alabama 36104 25 (334) 269-2343</p>	<p style="text-align: right;">Page 383</p> <p>1 APPEARANCES (CONTINUED): 2 3 ON BEHALF OF JOHNSON & JOHNSON DEFENDANTS: 4 KATHLEEN FRAZIER, ESQUIRE 5 SHOOK, HARDY & BACON, LLP 6 600 Travis Street 7 Suite 3400 8 Houston, Texas 77002-2926 9 (713) 227-8008 10 11 ON BEHALF OF THE IMERY'S DEFENDANTS: 12 JONATHAN F. DONATH, ESQUIRE 13 COUGHLIN DUFFY, LLP 14 350 Mount Kemble Avenue 15 Morristown, New Jersey 07962 16 (973) 267-0058 17 18 CATHERINE SLAVIN, ESQUIRE 19 GORDON & REES SCULLY MANSUKHANI, LLP 20 Three Logan Square 21 1717 Arch Street, Suite 610 22 Philadelphia, Pennsylvania 19103 23 (215) 717-4006 24 25</p>

2 (Pages 380 to 383)

Linda Loretz, Ph.D.

Page 384	Page 386
1 APPEARANCES (CONTINUED):	1 E X H I B I T S
2	2 (Attached to transcript)
3 ON BEHALF OF PTI:	3 LORETZ DEPOSITION EXHIBITS PAGE
4 JAMES W. MIZGALA, ESQUIRE	4 No. 46 E-mail re Response to Citizen's
5 TUCKER ELLIS, LLP	5 Petition on Talc / Latest Review
6 233 South Wacker Drive	6 of the Data, Bates JNJ 000426011 452
7 Suite 6950	7 No. 47 Draft Minutes Talc Interest Party
8 Chicago, Illinois 60606-9997	8 Task Force, April 12, 1994, Bates
9 (312) 624-6307	9 JNJTALC000376526 to 000376528 462
10	10 No. 48 Letter to Mary Wolfe from CTFA,
11 ALSO PRESENT:	11 Bates IMERYS 137977 to 137978 468
12	12 No. 49 Federal Register/Vol. 70, No. 200,
13 KATIE TUCKER (Paralegal - Beasley Allen)	13 Bates MUSCAT000004007 to 000004013 470
14 EMILY H. MANOSO, Staff Counsel, PCPC	14 No. 50 E-mail re Rothman Proposal for
15 THOMAS F. MYERS, Staff Counsel, PCPC	15 Updating CTFA Submission of Comments
16	16 to the NTP, Bates JNJ 000391715 to
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19	19 talc on contraceptive diaphragms and
20	20 risk of ovarian cancer: A meta-
21	21 analysis of nine observational
22	22 studies," Bates JNJ 000375876 to
23	23 000375883 479
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13	and Ovarian Cancer," Bates JNJ	13	Prevention (PDQ): Prevention -
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19	000023392 615	19	No. 79 "A Snapshot of Ovarian Cancer" 697
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5	Application of Cosmetic Tac and Risk	5	Alfred Wehner, Bates PCPC_MDL
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<p>1 PROCEEDINGS</p> <p>2 -----</p> <p>3 THE VIDEOGRAPHER: The time is 9:09 a.m.</p> <p>4 on October 1st, 2018. This is video 1, Volume II,</p> <p>5 in the continued deposition of Dr. Linda Loretz.</p> <p>6 A reminder to the witness, she is still</p> <p>7 under oath.</p> <p>8 CROSS-EXAMINATION</p> <p>9 BY MR. TISI:</p> <p>10 Q Good morning, Dr. Loretz.</p> <p>11 A Good morning.</p> <p>12 Q Just to remind the jury, what is --</p> <p>13 please state your name, please.</p> <p>14 A Linda Loretz.</p> <p>15 Q Okay. And you are a toxicologist?</p> <p>16 A Yes.</p> <p>17 Q Okay. And you're here represented by</p> <p>18 counsel?</p> <p>19 A Yes.</p> <p>20 Q My name is Chris Tisi. I represent</p> <p>21 women with ovarian cancer who claim that talcum</p> <p>22 powder products like Johnson & Johnson baby powder</p> <p>23 and Shower to Shower powder caused or contributed</p> <p>24 to their ovarian cancer.</p> <p>25 Do you understand that?</p>	<p>1 A Yes.</p> <p>2 Q Okay. And a 30(b)(6) deposition, just</p> <p>3 to get rid of all the legalese there, is a</p> <p>4 deposition where the company puts forward a</p> <p>5 witness to testify on behalf of the company.</p> <p>6 You understand that?</p> <p>7 A Yes.</p> <p>8 Q And you understand that your testimony</p> <p>9 is binding on the company?</p> <p>10 A Yes.</p> <p>11 Q Okay. And you're speaking not only as</p> <p>12 Dr. Loretz, but you're speaking on behalf of the</p> <p>13 Personal Care Products Council?</p> <p>14 A Yes.</p> <p>15 Q And by the Personal Care Products</p> <p>16 Council, you understand that we also mean an</p> <p>17 organization called CTFA?</p> <p>18 A Correct.</p> <p>19 Q Okay. And that's the predecessor name</p> <p>20 for the Personal Care Products Council, and I</p> <p>21 guess it was the Cosmetic Toiletry and</p> <p>22 Fragrance --</p> <p>23 A Association.</p> <p>24 Q -- Association, correct?</p> <p>25 A Correct.</p>
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<p>1 A Yes.</p> <p>2 Q Okay. And by the terms "talcum powder</p> <p>3 products," you understand that I mean cosmetic</p> <p>4 talc used in those products?</p> <p>5 A Yes.</p> <p>6 Q Okay. And if I had a bottle of either</p> <p>7 Shower to Shower here or Johnson's Baby Powder,</p> <p>8 what I'm referring to is everything that's in the</p> <p>9 bottle.</p> <p>10 Do you understand that?</p> <p>11 A Okay, yes.</p> <p>12 Q That includes fragrance, it includes</p> <p>13 whatever is mined from the -- from the mine,</p> <p>14 whatever is in that bottle.</p> <p>15 Do you understand?</p> <p>16 A Okay.</p> <p>17 Q I'm not talking about pure crystalline</p> <p>18 talc.</p> <p>19 A Okay.</p> <p>20 Q Okay? Unless I say otherwise.</p> <p>21 Have we ever met before?</p> <p>22 A I don't believe so.</p> <p>23 Q Okay. You know this is a continuation</p> <p>24 of a 30(b)(6) deposition that we -- we propounded</p> <p>25 on the Personal Care Products Council?</p>	<p>1 Q Yeah. And you understand your testimony</p> <p>2 is also binding on them as well?</p> <p>3 A Yes.</p> <p>4 Q Okay. You also understand that you are</p> <p>5 under oath, and your testimony -- testimony may be</p> <p>6 played for the court or jury to consider amongst</p> <p>7 all the other evidence in the case?</p> <p>8 A I do.</p> <p>9 Q Okay. I'm going to hand you what I</p> <p>10 would like to have marked as -- well, that has</p> <p>11 been marked as Exhibit 1 to your prior deposition.</p> <p>12 We don't have those exhibits here, but I do have a</p> <p>13 copy of it. I don't have a copy for all counsel.</p> <p>14 You are here pursuant to that Second</p> <p>15 Amended Notice of Deposition?</p> <p>16 A Okay, yes.</p> <p>17 Q Okay. All right.</p> <p>18 I'd like to talk to you a bit about what</p> <p>19 was done to prepare for this portion of your</p> <p>20 deposition. Your deposition -- this is a</p> <p>21 continuation of a deposition that happened I</p> <p>22 believe in July.</p> <p>23 A Yes.</p> <p>24 Q Okay. Between July and now, have you</p> <p>25 interviewed or spoken to any other people -- let's</p>

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<p>1 put your counsel aside for a moment -- any other 2 either employees, current or former employees, of 3 Personal Care Products Council? 4 A No, just counsel. Just my counsel 5 and -- 6 Q Have you spoken to any third-party 7 witnesses in this case, people -- for example, 8 employees of Johnson & Johnson, employees of -- of 9 Imerys, outside researchers? 10 A Not about this case, no. 11 Q Okay. What additional work have you 12 done to prepare yourself or further prepare 13 yourself to testify to the topics contained in 14 that notice of deposition? 15 A I met with my attorney for several days 16 reviewing records, minutes, e-mails, documents 17 related. 18 Q Have you spoken to John Bailey at all? 19 A No. 20 Q Have you spoken to John Bailey at all 21 since -- you know who John Bailey is? 22 A Yes. 23 Q Have you spoken to John Bailey at all 24 since -- at any time in this process, including 25 before your first deposition?</p>	<p>1 not prepared to testify to today as -- fully? 2 A Categories, I would say no. 3 Q Okay. Now, I'm going to ask you some 4 questions today relating to specific categories, 5 and I'll list them. 6 1(e), which is dissemination of medical 7 and scientific information on talcum powder and 8 ovarian cancer, 1(f), 1(g), 4(a), 4(c), and 9 categories 8 through 22. 10 I'm just doing that for the record, but 11 broadly they fall into two broad categories, and 12 I'm going to separate my questions to you into two 13 broad categories. Okay? 14 A Okay. 15 Q And the broad categories are this: 16 Communications with the Food and Drug 17 Administration about talcum power products and 18 ovarian cancer, including, for example, the 19 Citizen's Petition issue. 20 A Okay. 21 Q Okay? 22 A Yes. 23 Q The one area that I will not cover that 24 will be covered by one of my colleagues is the CIR 25 report.</p>
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<p>1 A No. 2 Q Have you spoken to any lawyers not your 3 own? 4 A The PCPC lawyers, Tom Myers and Emily 5 Manoso, but beyond that, no. 6 Q Okay. Have you reviewed the notice of 7 deposition that I placed before you, Exhibit 8 No. 1, to refamiliarize yourself with the topics 9 we're here to discuss today? 10 A I've reviewed it before. I haven't 11 reviewed it very, very recently, but -- 12 Q Okay. Is there any topic or topics in 13 that notice for which you have been designated 14 that you do not feel comfortable testifying to 15 today? In other words, that you are not -- your 16 investigation is not complete and you don't have 17 information about the topics. 18 A I mean, I guess I would just note that 19 obviously I wasn't here in the '80s, so I can only 20 go by the records that I have seen. But beyond 21 that, no. 22 Q I guess what I'm asking you, and this is 23 a process that is a little bit of a give and take 24 between you and me, and I -- I just want to ask 25 you, are there any categories there that you're</p>	<p>1 A Okay. 2 Q So you won't hear CIR from me. 3 But other than that, the communications 4 with the FDA will be issues I'll be asking you 5 about. 6 A Okay. 7 Q The second part of it is -- will be 8 about consultants and studies, people with whom 9 you consulted and studies that were performed or 10 not performed at the direction of or with the 11 cooperation with PCPC. 12 A Okay. 13 Q Okay. So just broadly speaking, the two 14 categories are communications with FDA except for 15 CIR, and consultants and -- and studies. 16 A Okay. 17 Q Okay? 18 A Yes. 19 Q All right. So let's get started. 20 I want to talk about first 21 communications with the FDA, and I'd like to use 22 as kind of a fulcrum of our discussions the 23 Citizen's Petition, and you know what I mean by 24 the "Citizen's Petition"? 25 A Yes.</p>

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<p>1 Q Okay. To help us really understand</p> <p>2 this, I prepared a timeline --</p> <p>3 MR. LOCKE: Counsel, can I just ask, I</p> <p>4 mean there were a number of Citizen's Petitions.</p> <p>5 Can you --</p> <p>6 MR. TISI: I'm going to be clear.</p> <p>7 MR. LOCKE: Okay.</p> <p>8 MR. TISI: I'm giving a timeline here,</p> <p>9 and we'll --</p> <p>10 MR. LOCKE: Okay.</p> <p>11 MR. TISI: -- we'll do that.</p> <p>12 BY MR. TISI:</p> <p>13 Q So to begin, I'm going to start with the</p> <p>14 most recent Citizen's Petition, the one that was</p> <p>15 filed in 2008.</p> <p>16 A Yes, mm-hmm.</p> <p>17 Q And you're familiar with that, correct?</p> <p>18 A Yes.</p> <p>19 Q And to help us understand the context in</p> <p>20 which that Citizen's Petition was filed and what</p> <p>21 it is, and we haven't explained it to the jury yet</p> <p>22 and we will, I've prepared a little bit of a</p> <p>23 timeline here. And we're going to kind of mark</p> <p>24 some things so that everybody understands the</p> <p>25 historical context in which that petition was</p>	<p>1 A 2006, no?</p> <p>2 Q 2006. Excuse me.</p> <p>3 A Yes.</p> <p>4 Q Yeah. And the Cancer Coalition</p> <p>5 Prevention citizens filed with the FDA, and that's</p> <p>6 in 2008.</p> <p>7 A Yes.</p> <p>8 Q Okay. And there were other things.</p> <p>9 Those are already on the chart. You agree with</p> <p>10 those?</p> <p>11 A Yes.</p> <p>12 Q Okay. Let's talk for a moment what your</p> <p>13 understanding -- first of all, in the course of</p> <p>14 your work with the PCPC, have you had occasions to</p> <p>15 deal with Citizen's Petitions before, or is this</p> <p>16 the only time that this happened?</p> <p>17 A Before this, this was probably the first</p> <p>18 one. I mean we -- we filed a Citizen's Petitions</p> <p>19 ourselves that came after this. Nothing to do</p> <p>20 with talc.</p> <p>21 Q Right. And so you're familiar with the</p> <p>22 process?</p> <p>23 A Yes.</p> <p>24 Q Okay. So would you tell the members of</p> <p>25 the jury a little bit about what a Citizen's</p>
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<p>1 actually filed.</p> <p>2 And I'm going to give a copy to counsel,</p> <p>3 and we're going to hopefully fill this out</p> <p>4 together, and you correct me if I'm wrong on</p> <p>5 any -- on anything I write on here.</p> <p>6 And we're going to mark this as Exhibit</p> <p>7 No. 41.</p> <p>8 (Exhibit No. 41 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. TISI:</p> <p>11 Q And we may come back to this during the</p> <p>12 course -- back and forth to this during the</p> <p>13 deposition, so I'm going to ask you to kind of --</p> <p>14 we'll kind of put it aside and bring it back and</p> <p>15 all that.</p> <p>16 And just for the members of the jury,</p> <p>17 we've marked on here, we started with 1994, and</p> <p>18 there's a reason why I've done that, which will</p> <p>19 become apparent, and then there's the National</p> <p>20 Toxicology Program 10th Report on Carcinogens</p> <p>21 that's in the year 2000.</p> <p>22 You know what I'm talking about?</p> <p>23 A Yes.</p> <p>24 Q Okay. The IARC review which was 2005.</p> <p>25 Correct?</p>	<p>1 Petition is to the best of your understanding.</p> <p>2 A It's -- it's --</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: It's going to be a very</p> <p>5 simple thing, because I -- I --</p> <p>6 BY MR. TISI:</p> <p>7 Q Simple is -- simple is always better.</p> <p>8 A -- I have a lot of details. I mean</p> <p>9 it's -- it's -- someone can petition FDA to</p> <p>10 request something through a process. I believe</p> <p>11 the process is probably spelled out in the Code of</p> <p>12 Federal Regulations. They can request something</p> <p>13 to FDA, and then FDA has, I believe, an obligation</p> <p>14 to respond within a certain amount of time,</p> <p>15 although they can -- they can respond by saying</p> <p>16 we've gotten it and we're reviewing it, and then</p> <p>17 they need to eventually respond to it.</p> <p>18 Q And are there opportunities for other</p> <p>19 interested parties to file comments to that</p> <p>20 petition?</p> <p>21 A Yes.</p> <p>22 Q Okay. And PCPC has on occasion actually</p> <p>23 filed Citizen's Petitions themselves.</p> <p>24 A Yes.</p> <p>25 Q And we're aware that the -- a Citizen's</p>

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<p>1 Petition was filed by a group called the Cancer 2 Prevention Coalition seeking a cancer warning on 3 cosmetic talc products in 2008. Correct? 4 A Yes. 5 Q Okay. And that was actually filed -- 6 that was actually filed in May of 2008? 7 A I don't remember. 8 Q Okay. Let's see if I can help you here. 9 (Exhibit No. 42 was marked for 10 identification.) 11 BY MR. TISI: 12 Q I'm going to hand you what I've had 13 marked as Exhibit No. 42. 14 Do you recognize this? 15 A Yes. 16 Q Okay. Is this the Citizen's -- is this 17 a Citizen's Petition that was filed on behalf of 18 the Cancer Prevention Coalition with the Food and 19 Drug Administration in -- on May 13th, 2008? 20 A That's what it looks to be, yes. 21 Q Okay. And you're familiar with that 22 document? 23 A Yes. 24 Q And -- 25 MR. TISI: Can we bring this document</p>	<p>1 University of Illinois at Chicago School of Public 2 Health. 3 A Correct. That's what it says. 4 Q And he filed a petition, and it's 5 actually at the very top, it says: "A petition 6 seeking a cancer warning on cosmetic talc 7 products." Do you see that? 8 A Yes. 9 Q Okay. And is this -- and I think you 10 had indicated that nobody from Personal Care 11 Products Council had ever contacted Dr. Epstein to 12 talk to him about the basis for his petition. 13 A Not that I'm aware. 14 Q Okay. And in this document, he was -- 15 and you're familiar with this document, right? 16 A Yes. 17 Q Okay. And Dr. Epstein, if I could 18 summarize, was writing about the potential link 19 between ovarian cancer and -- talcum powder 20 products and ovarian cancer, correct? 21 A Right. 22 Q And this issue was not a new issue, was 23 it? 24 A No. 25 Q Okay. The issue of the connection</p>
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<p>1 up. 2 BY MR. TISI: 3 Q The document in front of you, it was 4 filed by a Dr. Epstein. Do you know that? 5 A Yes. 6 Q Has anyone with PCPC ever sought to meet 7 with Dr. Epstein, if you know? 8 A Not that I'm aware. 9 Q And he was a professor of occupational 10 and environmental medicine at the University of 11 Illinois Chicago Medical Center. That's in the 12 first paragraph. 13 MR. LOCKE: Objection. 14 THE VIDEOGRAPHER: Counsel, can we go 15 off the record? 16 The time is 9:23 a.m. We're going off 17 the record. 18 (Technical difficulties.) 19 THE VIDEOGRAPHER: The time is 9:27 20 a.m., and we're back on the record. 21 BY MR. TISI: 22 Q Just to reask the question, if you look 23 at the first paragraph, this Dr. Epstein 24 identifies himself as the professor emeritus of 25 occupational and environmental medicine,</p>	<p>1 between talcum powder products and ovarian cancer 2 was one that went back into the 1970s, correct? 3 A I think the '80s. I thought it was the 4 first paper published in 1982 that I'm aware of. 5 Q Okay. Then that's what -- we'll use 6 that. 7 And if we can go back to our timeline, 8 if I wrote on top of here that -- concerns that -- 9 MR. TISI: Off the record? 10 (A discussion was held off the record.) 11 MR. TISI: We do need to see that. 12 THE VIDEOGRAPHER: The time is 9:30 a.m. 13 We're going off the record. 14 (Pause in the proceedings.) 15 THE VIDEOGRAPHER: The time is 9:31 a.m. 16 We're back on the record. 17 BY MR. TISI: 18 Q And, Dr. Loretz, I'm sorry for the 19 technical difficulties we're having here. I took 20 the break to write down what I think we agreed. 21 Beginning in about 1982, concerns were 22 raised that talcum powder products may cause or 23 contribute to ovarian cancer; is that correct? 24 A That's correct. 25 Q Okay. And starting in 1982, that issue</p>

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<p>1 was an issue that was one that wasn't just one</p> <p>2 that was raised and forgotten, it was an issue</p> <p>3 that was persistently discussed in the medical and</p> <p>4 scientific literature from that point forward.</p> <p>5 Fair?</p> <p>6 A Yes.</p> <p>7 Q Okay. So it was discussed in the '80s,</p> <p>8 '90s, 2000s, and in fact, it's still being</p> <p>9 discussed today.</p> <p>10 A Yes.</p> <p>11 Q And by 2008, which would have been about</p> <p>12 20 -- two decades plus since those initial</p> <p>13 reports, the Cancer Prevention Coalition filed a</p> <p>14 petition to the FDA that asked the FDA to mandate,</p> <p>15 require, that all talcum powder products have some</p> <p>16 kind of warning for ovarian cancer. True?</p> <p>17 A That's what the petition says, yes.</p> <p>18 Q Okay. And so if you go to page 2 of the</p> <p>19 letter.</p> <p>20 MR. TISI: Can you please go back?</p> <p>21 BY MR. TISI:</p> <p>22 Q Section A, it says: "Agency action</p> <p>23 requested," and point number 1, it says:</p> <p>24 "Immediately require cosmetic talcum powder</p> <p>25 products to bear labels with a prominent warning</p>	<p>1 Q Okay. So taking off your hat of</p> <p>2 Dr. Loretz and putting on your hat as Personal</p> <p>3 Care Products Council, can you tell us when the</p> <p>4 Personal Care Products Council first became aware</p> <p>5 of this petition?</p> <p>6 A I'm sure it was soon after it was filed.</p> <p>7 Q So it was filed in May of 2008. It</p> <p>8 would have been approximately May of 2008.</p> <p>9 A Yes. I believe so.</p> <p>10 Q All right. Let's put that aside for a</p> <p>11 moment. We'll come back to that.</p> <p>12 Now, in July of 2009, did the Personal</p> <p>13 Care Products Council file a white paper with the</p> <p>14 FDA or comments with the FDA opposing the Cancer</p> <p>15 prevention -- Prevention Coalition petition?</p> <p>16 A Yes.</p> <p>17 Q And that was filed on July 21st, 2009.</p> <p>18 Correct?</p> <p>19 A I don't recall.</p> <p>20 Q Let me see if I can provide you with</p> <p>21 what I have marked as Exhibit No. 43.</p> <p>22 (Exhibit No. 43 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. TISI:</p> <p>25 Q Is that the PCPC -- I'm sorry.</p>
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<p>1 such as 'Frequent talc application in the female</p> <p>2 genital area is responsible for major risks of</p> <p>3 ovarian cancer.'"</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Did I read that correctly?</p> <p>7 A That's what it says.</p> <p>8 Q Okay. And Dr. Epstein also asked to be</p> <p>9 heard by the FDA on this petition, correct?</p> <p>10 A That's what it says, yes.</p> <p>11 Q Okay. So not only did he file a letter</p> <p>12 requesting that the -- a warning be added to</p> <p>13 talcum powder products, but he also wanted to meet</p> <p>14 with them, correct?</p> <p>15 A That's what it says, yes.</p> <p>16 Q All right. You became -- the Personal</p> <p>17 Care Products Council became aware of this</p> <p>18 petition -- do you remember when it became aware</p> <p>19 of this petition?</p> <p>20 A I really don't.</p> <p>21 Q Okay. Do you remember the circumstances</p> <p>22 under which it became aware of this petition?</p> <p>23 A I don't remember the details, no. I'm</p> <p>24 sure it was -- I'm sure it was soon after it was</p> <p>25 filed, but I don't remember the details.</p>	<p>1 Is this the response of the Personal</p> <p>2 Care Products Council to the Epstein petition to</p> <p>3 add a warning?</p> <p>4 A Yes.</p> <p>5 Q Okay. Now, is it fair to say, and if</p> <p>6 you go to the -- the position of the Personal Care</p> <p>7 Products Council is the addition of a warning</p> <p>8 label on products such as Johnson & Johnson's baby</p> <p>9 powder and Shower to Shower would be inappropriate</p> <p>10 and unnecessary?</p> <p>11 A You're reading that somewhere?</p> <p>12 Q It's the very last -- second to last</p> <p>13 paragraph at the end.</p> <p>14 A Yes.</p> <p>15 Q And so just to make sure that we're kind</p> <p>16 of 2000 -- at 30,000 feet, the petition was filed</p> <p>17 asking for a warning. The petition of the</p> <p>18 Personal Care Products Council was no warning was</p> <p>19 necessary.</p> <p>20 A That's correct.</p> <p>21 Q In this petition did the Personal Care</p> <p>22 Products Council lay out the standard for when a</p> <p>23 warning is appropriate, if you know?</p> <p>24 A I believe our response to the petition</p> <p>25 was to look at the science on talcum powder and</p>

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<p>1 ovarian cancer.</p> <p>2 Q Okay. But the question that I asked is</p> <p>3 a different one.</p> <p>4 The standard of when a warning is</p> <p>5 required is a standard that you're familiar with?</p> <p>6 A That sounds more like a legal concept,</p> <p>7 so I'm not sure that I am.</p> <p>8 Q Well, does the Personal Care Products</p> <p>9 Council provide a labeling manual for its members?</p> <p>10 A We do, but it's -- it's -- yes, it's a</p> <p>11 summary of existing labeling requirements,</p> <p>12 regulatory requirements.</p> <p>13 Q Right. Does this petition --</p> <p>14 Dr. Epstein asked for a label to be added,</p> <p>15 correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q And this opposes the addition of a</p> <p>20 label, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Did the Personal Care Products Council</p> <p>25 in any way analyze or -- or discuss the standard</p>	<p>1 Loretz. You're speaking here as a -- as the</p> <p>2 organization.</p> <p>3 A Okay.</p> <p>4 Q And the organization is responding to a</p> <p>5 request to add a warning. Right?</p> <p>6 A Yes.</p> <p>7 Q And the -- presumably -- I mean, maybe I</p> <p>8 should ask you the question: Did PCPC consult</p> <p>9 with the requirements for adding a warning before</p> <p>10 responding to this petition?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I -- I mean, we don't</p> <p>13 agree with the petitioner's rationale for adding a</p> <p>14 warning.</p> <p>15 BY MR. TISI:</p> <p>16 Q I understand you -- you have a</p> <p>17 difference in the weight of the evidence that</p> <p>18 would support or not support a warning.</p> <p>19 My question is, did you understand at</p> <p>20 the time the standard for what -- what would</p> <p>21 require a warning or not?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: I think it was our</p> <p>24 understanding this would not require a warning.</p> <p>25 BY MR. TISI:</p>
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<p>1 for providing when a label -- to add a warning on</p> <p>2 a cosmetic product is required?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: We -- as I say, what we</p> <p>5 did was we reviewed the science on ovarian cancer,</p> <p>6 talcum powder, and our position is that there is</p> <p>7 not evidence of a causative role, and therefore we</p> <p>8 did not believe a -- a label is necessary.</p> <p>9 MR. TISI: Okay. Move to strike.</p> <p>10 BY MR. TISI:</p> <p>11 Q My question was a different one.</p> <p>12 Does this opposition that was filed in</p> <p>13 July of 2009 contain any discussion of what the</p> <p>14 standard is?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: No, it addresses the</p> <p>17 science.</p> <p>18 BY MR. TISI:</p> <p>19 Q Okay. Do you know whether or not the</p> <p>20 standard requires that causation be proven before</p> <p>21 a warning be added?</p> <p>22 A I -- I think that sounds like a legal</p> <p>23 question. I -- I --</p> <p>24 Q I'm asking you since this was filed</p> <p>25 on -- you're -- you're speaking here not as Linda</p>	<p>1 Q Well, what was the standard?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: I'm not sure I understand</p> <p>4 that question.</p> <p>5 BY MR. TISI:</p> <p>6 Q Okay. Did the standard require that --</p> <p>7 and if you don't know the answer, you don't know</p> <p>8 the answer, okay?</p> <p>9 But does the standard for providing a</p> <p>10 warning require that causation be proven, be</p> <p>11 unequivocal?</p> <p>12 MR. LOCKE: Objection. That's beyond</p> <p>13 the scope.</p> <p>14 You can answer in your personal</p> <p>15 capacity.</p> <p>16 THE WITNESS: I'm not sure what you mean</p> <p>17 by the standard for requiring a warning.</p> <p>18 BY MR. TISI:</p> <p>19 Q Well, this is -- this is a response to a</p> <p>20 request that a warning be added.</p> <p>21 A Correct. Which FDA later said it</p> <p>22 doesn't require a warning.</p> <p>23 Q That's not --</p> <p>24 MR. TISI: Move to strike.</p> <p>25 BY MR. TISI:</p>

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<p>1 Q Okay. My -- my -- my question is, did 2 the PCPC consult what the legal -- what the legal 3 standard was for when a warning is required? 4 MR. LOCKE: Objection. 5 THE WITNESS: I mean, I -- I -- I think 6 it's fair to say we have a lot of lawyers at PCPC, 7 and if they felt this were inappropriate from a 8 legal standpoint to have this position, we would 9 not have that position. 10 BY MR. TISI: 11 Q Did they set out what the standard is in 12 the letter? Is there anything in this letter -- 13 first of all, who drafted this cover letter? 14 A It was either myself or John Bailey. 15 Q Okay. Did you consult with -- either 16 one of you consult with what the standard is for 17 when a warning is required before writing this 18 letter? 19 MR. LOCKE: Objection. 20 THE WITNESS: I'm -- again, I'm not 21 quite sure when what you mean "when a warning was 22 required." By whom? 23 BY MR. TISI: 24 Q Well, you -- you know -- do you know 25 that warnings are added when a cosmetic product</p>	<p>1 level of evidence that's required before a label 2 is added? 3 MR. LOCKE: Objection. Beyond the 4 scope. 5 BY MR. TISI: 6 Q If you don't know, you don't know. 7 A Yeah, I -- I guess I would say I don't 8 know, but I -- 9 Q That's fine. But you wrote this letter 10 anyway, you or Dr. Bailey wrote this letter to the 11 FDA responding to requests for requiring a label. 12 A Again, I would say certainly there was 13 awareness within PCPC, and it was felt that this 14 was appropriate as a response. 15 Q Right. And there was -- but there was 16 no discussion about what the standard is under the 17 Code of Federal Regulations in this -- in this 18 letter, correct? 19 MR. LOCKE: Objection. 20 THE WITNESS: And again, I would just 21 say our -- our view was that -- that there was not 22 a need for warning because of the lack of 23 evidence. 24 BY MR. TISI: 25 Q Okay. Well, as -- as we discussed</p>
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<p>1 may cause -- there's evidence that they may cause 2 a potential harm? 3 MR. LOCKE: Objection. Beyond the 4 scope. 5 You can answer in your personal 6 capacity. 7 THE WITNESS: I'm sorry. What's the 8 question? 9 BY MR. TISI: 10 Q Do you know that warnings can be added 11 voluntarily when there's evidence that the product 12 may cause a potential harm? 13 MR. LOCKE: Same objection, and to form. 14 THE WITNESS: And as our position being 15 that there was not support for that harm, we would 16 not have supported adding a voluntary label. 17 BY MR. TISI: 18 Q I -- I understand. 19 A We would not have said, yes, this should 20 be labeled. 21 Q But should -- do you not understand what 22 the standard is for a label? 23 MR. LOCKE: Objection. 24 BY MR. TISI: 25 Q What is -- what is the -- what is the</p>	<p>1 before, this issue was one that was debated in the 2 medical and scientific community for almost 25 3 years before this petition was filed, correct? 4 A It was a topic, yes. 5 Q All right. And some epidemiologists 6 looking at the evidence felt that there -- there 7 was sufficient evidence to raise a causal 8 inference, correct? 9 MR. LOCKE: Objection. 10 BY MR. TISI: 11 Q Including Dr. Epstein. 12 MR. LOCKE: Objection. 13 THE WITNESS: Dr. Epstein did, but I 14 think the literature, as we point out and as we 15 had our epidemiologists point out, that there is a 16 lot of inconsistency. 17 BY MR. TISI: 18 Q Understood. My -- I understand that's 19 your position. 20 My question, though, is a different one, 21 Dr. Loretz. There were epidemiologists and -- and 22 scientists in the medical and scientific 23 communication who disagreed with the PCPC's view 24 of the sufficiency of the evidence. This was an 25 active debate, correct?</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: That's probably fair to</p> <p>3 say, and certainly Dr. Epstein disagreed.</p> <p>4 BY MR. TISI:</p> <p>5 Q Right. And there were others. I mean</p> <p>6 Dr. Cramer, another -- another doctor who you are</p> <p>7 familiar with, wrote and published -- and</p> <p>8 published in the literature several -- several of</p> <p>9 the studies. You know that he felt and published</p> <p>10 that there was an inference of causation, true?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I believe that would be</p> <p>13 true, and then the -- there were epidemiologists</p> <p>14 who did not agree with that.</p> <p>15 BY MR. TISI:</p> <p>16 Q Fine. Okay. And that kind of</p> <p>17 illustrates a point that I think is important to</p> <p>18 make here.</p> <p>19 Looking at the evidence that -- some of</p> <p>20 which was summarized in this letter, reasonable --</p> <p>21 scientists looking at the evidence could reach</p> <p>22 different conclusions looking at that evidence,</p> <p>23 and in fact, did reach different conclusions,</p> <p>24 correct?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 Citizen's Petition," and that would be July 2009.</p> <p>2 Okay?</p> <p>3 A Yes.</p> <p>4 MR. LOCKE: I'm just going to object. I</p> <p>5 mean it says "Comments" on it. It doesn't say</p> <p>6 "opposition to," but --</p> <p>7 BY MR. TISI:</p> <p>8 Q But I think -- I think the testimony was</p> <p>9 this was in opposition to adding a warning,</p> <p>10 correct?</p> <p>11 A Yes. We did not think a warning was</p> <p>12 necessary.</p> <p>13 Q Okay. So let's put that aside for a</p> <p>14 moment.</p> <p>15 Oh, I'm sorry, before -- before we leave</p> <p>16 this document, if you go to page 4 of 39 of this</p> <p>17 document, you attach a report.</p> <p>18 A Yes.</p> <p>19 Q PCPC attaches a report. And this is a</p> <p>20 report by a group called the Meta-Analysis</p> <p>21 Research Group. Correct?</p> <p>22 A Yes.</p> <p>23 Q Okay. And that's a group that you're</p> <p>24 familiar with?</p> <p>25 A Yes.</p>
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<p>1 THE WITNESS: Yeah, there were different</p> <p>2 opinions.</p> <p>3 BY MR. TISI:</p> <p>4 Q Okay. And there were different opinions</p> <p>5 based upon the evidence, correct?</p> <p>6 A I don't want to go to what the -- what</p> <p>7 the thoughts were, but I mean, there's a body of</p> <p>8 scientific literature, yes.</p> <p>9 Q Right. And that's not unusual. You've</p> <p>10 been in this business for -- for a while.</p> <p>11 Scientists and doctors look at -- look at the</p> <p>12 evidence, and some -- they can often disagree</p> <p>13 about evidence, correct?</p> <p>14 A That's true.</p> <p>15 Q All right. All right. So let's put</p> <p>16 this opposition to the Citizen's Petition on our</p> <p>17 timeline here, and this was --</p> <p>18 MR. TISI: Maybe we can switch back to</p> <p>19 this.</p> <p>20 THE VIDEOGRAPHER: It is. It's in</p> <p>21 process.</p> <p>22 MR. TISI: If I can see if I can write</p> <p>23 it.</p> <p>24 BY MR. TISI:</p> <p>25 Q This would be "PCPC opposition to</p>	<p>1 Q Okay. And it was prepared by a</p> <p>2 Dr. Michael Huncharek?</p> <p>3 A Yes.</p> <p>4 Q And a Dr. Joshua Muscat?</p> <p>5 A Correct.</p> <p>6 Q And they both identify themselves as</p> <p>7 being with the Meta-Analysis Research Group.</p> <p>8 A As well as other affiliations, but yes.</p> <p>9 Q All right. And we'll get into this in a</p> <p>10 minute, but this report was initially written for</p> <p>11 Johnson & Johnson, correct?</p> <p>12 A Yes.</p> <p>13 Q And it was then -- in fact, earlier</p> <p>14 versions of this have "Prepared for Johnson &</p> <p>15 Johnson." This version that was submitted to the</p> <p>16 FDA says "Prepared for the Personal Care Products</p> <p>17 Council." Correct?</p> <p>18 A That could be, yes.</p> <p>19 Q Okay. And it was actually prepared for</p> <p>20 Johnson & Johnson, but --</p> <p>21 A Originally.</p> <p>22 Q Originally. It was not prepared for or</p> <p>23 initiated by the Personal Care Products Council,</p> <p>24 correct?</p> <p>25 A We took it over, though, yes.</p>

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<p style="text-align: right;">Page 424</p> <p>1 Q Right.</p> <p>2 A I mean, and submitted it, yes.</p> <p>3 Q All right. But J&J did not submit the</p> <p>4 report. The Personal Care Products Council did.</p> <p>5 A Correct.</p> <p>6 Q Now, I think in your prior deposition</p> <p>7 you said you had met Dr. Huncharek and Dr. Muscat</p> <p>8 before, correct?</p> <p>9 A I'm not sure if I ever met</p> <p>10 Dr. Huncharek. I know I met Dr. Muscat once upon</p> <p>11 a time.</p> <p>12 Q Okay. Had you had occasion to</p> <p>13 communicate with them either on teleconferences or</p> <p>14 by e-mail?</p> <p>15 A I had spoken to Dr. Huncharek.</p> <p>16 Q Okay. How often?</p> <p>17 A Once or twice.</p> <p>18 Q Okay. Now, on page 6 of this document</p> <p>19 is an introduction. Do you see that?</p> <p>20 A Yes.</p> <p>21 Q It identifies -- the second paragraph</p> <p>22 identifies this report as "an independent review</p> <p>23 of the relevant data." Do you see that?</p> <p>24 A Sorry, where?</p> <p>25 Q Second -- second paragraph, second to</p>	<p style="text-align: right;">Page 426</p> <p>1 conclusions at all. That's a --</p> <p>2 Q Right. And in fact, these -- these</p> <p>3 doctors, Meta-Analysis Research Group, had been</p> <p>4 consultants to the talc industry before this,</p> <p>5 correct?</p> <p>6 A They had --</p> <p>7 MR. LOCKE: Objection.</p> <p>8 BY MR. TISI:</p> <p>9 Q I'm sorry. You may answer the question.</p> <p>10 A They had, yes. Or Dr. Muscat had</p> <p>11 reviewed for NTP.</p> <p>12 Q Okay. And you were aware through</p> <p>13 Crowell & Moring that they were both retained to</p> <p>14 provide information on NTP for the 12 -- 12th</p> <p>15 review on carcinogens, correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: I'm not sure if --</p> <p>18 BY MR. TISI:</p> <p>19 Q You ever heard of Crowell & Moring?</p> <p>20 A I've heard of them, yes.</p> <p>21 Q Okay. Do you know -- did you</p> <p>22 communicate with them through Crowell & Moring?</p> <p>23 A Communicate with?</p> <p>24 Q Huncharek and Muscat.</p> <p>25 A Oh, no. No.</p>
<p style="text-align: right;">Page 425</p> <p>1 last sentence.</p> <p>2 A Okay.</p> <p>3 Q It identifies this as "an independent</p> <p>4 review of the relevant data."</p> <p>5 A Okay.</p> <p>6 Q Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Okay. This was not an independent</p> <p>9 review of the relevant data, was it?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: I think it depends how you</p> <p>12 define "independent." I mean these -- the</p> <p>13 epidemiologists that were retained -- I mean,</p> <p>14 first of all, this was on behalf of our members,</p> <p>15 not just J&J. They initiated the contact and got</p> <p>16 the report writing started.</p> <p>17 I think independent in the sense that</p> <p>18 these were the conclusions of these</p> <p>19 epidemiologists.</p> <p>20 BY MR. TISI:</p> <p>21 Q Right. But this report was written with</p> <p>22 Johnson & Johnson and Imerys's input, correct?</p> <p>23 A We probably had all of our members who</p> <p>24 were interested are allowed -- you know, would</p> <p>25 review it, but that doesn't mean we change the</p>	<p style="text-align: right;">Page 427</p> <p>1 Q Did you -- and you know that they</p> <p>2 appeared as an industry representative for --</p> <p>3 Dr. Muscat appeared at the IARC proceedings as an</p> <p>4 industry member?</p> <p>5 A I do know that.</p> <p>6 MR. LOCKE: Well, wait -- wait one</p> <p>7 second. When you say "they appeared," who are you</p> <p>8 referring to?</p> <p>9 MR. TISI: I said Dr. Muscat.</p> <p>10 MR. LOCKE: Okay.</p> <p>11 BY MR. TISI:</p> <p>12 Q Are you aware of that?</p> <p>13 A I'm aware of that, yes.</p> <p>14 Q You know who Robert Glenn is, don't you?</p> <p>15 A I know who he is.</p> <p>16 Q Okay. You know he is with Crowell &</p> <p>17 Moring?</p> <p>18 A Yes.</p> <p>19 Q And you received e-mails from him,</p> <p>20 correct?</p> <p>21 A Well, not in relation to this.</p> <p>22 Q Well, with relation to Huncharek and</p> <p>23 Muscat, correct?</p> <p>24 A Only -- the only -- the only thing I</p> <p>25 believe I received e-mails from him, just as a --</p>

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<p>1 being copied was related to the IARC review.</p> <p>2 Q Okay. And you also understand -- we'll</p> <p>3 talk about this in a moment -- they let you know</p> <p>4 that there were publications that were being</p> <p>5 planned by Huncharek and Muscat, true?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm not sure. I may have</p> <p>8 known.</p> <p>9 BY MR. TISI:</p> <p>10 Q Okay. We'll talk about those. We'll</p> <p>11 talk about those.</p> <p>12 But -- but the bigger picture, Doctor,</p> <p>13 is that Huncharek and Muscat were people who had</p> <p>14 been in communication with the talc industry going</p> <p>15 back to at least 2000 and perhaps before.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: Muscat in 2000, I'm</p> <p>18 certainly aware of that.</p> <p>19 BY MR. TISI:</p> <p>20 Q And you said you had spoken to Huncharek</p> <p>21 as well.</p> <p>22 A I spoke to him I believe around the time</p> <p>23 of this, I think. I spoke to him once, I know</p> <p>24 that, and I can't remember exactly when it was.</p> <p>25 Q Okay. Now, prior to the talc -- prior</p>	<p>1 what Dr. Huncharek did.</p> <p>2 Q Okay. Do you know whether or not they</p> <p>3 were an organization that was a contract research</p> <p>4 organization? For example, do you know whether or</p> <p>5 not they were litigation consultants? Do you know</p> <p>6 whether or not they were -- you know, what they</p> <p>7 were?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: I mean I think we were</p> <p>10 familiar with them from doing this. This to me --</p> <p>11 so we know they did this kind of meta-analysis,</p> <p>12 which again was something I know that both</p> <p>13 Dr. Huncharek and Dr. Muscat did. So...</p> <p>14 MR. TISI: I'm going to -- I'm going to</p> <p>15 actually move to strike.</p> <p>16 BY MR. TISI:</p> <p>17 Q My question was, do you know -- or did</p> <p>18 you do any due diligence as to what Meta-Analysis</p> <p>19 Research Group was?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: No, because we knew who</p> <p>22 the authors were.</p> <p>23 (Exhibit No. 44 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. TISI:</p>
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<p>1 to this publication, had you ever heard of the</p> <p>2 Meta-Analysis Research Group ever?</p> <p>3 MR. LOCKE: When you refer to "this</p> <p>4 publication," you mean Exhibit 43?</p> <p>5 MR. TISI: Correct.</p> <p>6 BY MR. TISI:</p> <p>7 Q Let me -- let me rephrase the question,</p> <p>8 because -- to be clear.</p> <p>9 Prior to these comments that were</p> <p>10 submitted to the FDA in July of 2009 under the</p> <p>11 letterhead of Meta-Analysis Research Group, had</p> <p>12 you ever had occasion to come across Meta-Analysis</p> <p>13 Research Group before then?</p> <p>14 A I honestly don't know. I believe</p> <p>15 Dr. Muscat's affiliation was not that in 2000.</p> <p>16 Q It was American Health Foundation.</p> <p>17 A That's what I remember as well.</p> <p>18 Q Okay. So my question is, did you --</p> <p>19 prior to submitting this independent report on</p> <p>20 behalf of the industry by a group called</p> <p>21 Meta-Analysis Research Group, did PCPC do any due</p> <p>22 diligence as to who Meta-Analysis Research Group</p> <p>23 is and what their focus was?</p> <p>24 A I -- I think the assumption was that</p> <p>25 they were doing meta-analysis, which I know is</p>	<p>1 Q Okay. I'm going to show you Exhibit</p> <p>2 No. 44.</p> <p>3 And I'm not concerned with the front</p> <p>4 pages of it. But with an attachment.</p> <p>5 Here you go.</p> <p>6 MR. TISI: I'm sorry? Oh, Tom, I'm</p> <p>7 sorry, here you go.</p> <p>8 MR. LOCKE: Thank you.</p> <p>9 MR. TISI: Yep.</p> <p>10 BY MR. TISI:</p> <p>11 Q And if you go to the last -- and I'll</p> <p>12 just represent to you, this is a proposal from</p> <p>13 Dr. Huncharek to Bob Glenn to do certain papers</p> <p>14 and research on behalf of Imerys in 2004.</p> <p>15 But attached to it --</p> <p>16 MR. LOCKE: Let's let the witness just</p> <p>17 read it first a second, just flip through the</p> <p>18 pages.</p> <p>19 MR. TISI: Oh, she can certainly do</p> <p>20 that, Tom.</p> <p>21 BY MR. TISI:</p> <p>22 Q And I'm going to ask you on the -- about</p> <p>23 the brochure that's attached on page 5.</p> <p>24 A (Peruses document.)</p> <p>25 Q Since you took the time to read it, let</p>

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<p>1 me just ask you the question. Do you see that</p> <p>2 this is a proposal to write two papers, one on</p> <p>3 meta-analysis on diaphragms and one a critical</p> <p>4 review of the talc literature?</p> <p>5 A Yes.</p> <p>6 Q Okay. You know that they did publish</p> <p>7 two articles relating to that very specific --</p> <p>8 those two specific topics, correct?</p> <p>9 A I believe so, yes.</p> <p>10 Q Okay. And so this is a proposal by --</p> <p>11 by Dr. Huncharek to write such articles to</p> <p>12 Mr. Glenn, who I will represent to you was with</p> <p>13 the lawyers for Crowell & Moring for Imerys.</p> <p>14 A Okay.</p> <p>15 Q Okay. Attached to that is a brochure</p> <p>16 from the Meta-Analysis Research Group. Do you see</p> <p>17 that?</p> <p>18 A I guess this is --</p> <p>19 MR. LOCKE: Page 5.</p> <p>20 THE WITNESS: Okay. Okay.</p> <p>21 BY MR. TISI:</p> <p>22 Q Okay. This is a brochure. Did you</p> <p>23 ever -- I think I -- I asked you before, but did</p> <p>24 you ever ask -- first of all, the report that was</p> <p>25 filed on behalf of the FDA, I believe your answers</p>	<p>1 litigation?</p> <p>2 A I'm not sure. I knew that Dr. Muscat</p> <p>3 was deposed, but I don't -- I don't think that's</p> <p>4 the same as what you're asking.</p> <p>5 Q And so my question to you is, did it</p> <p>6 matter to you when you were submitting this on</p> <p>7 behalf of -- to the FDA as to whether or not these</p> <p>8 consultants who -- were basically people who would</p> <p>9 be involved in litigation?</p> <p>10 MR. LOCKE: Objection. Do you mean --</p> <p>11 BY MR. TISI:</p> <p>12 Q Did you think about that?</p> <p>13 MR. LOCKE: Do you mean -- when you say</p> <p>14 "this," you're referring to Exhibit 43, the</p> <p>15 comments?</p> <p>16 MR. TISI: Correct, in 2009.</p> <p>17 BY MR. TISI:</p> <p>18 Q Did you want to know -- did you even</p> <p>19 think to know whether or not these witnesses,</p> <p>20 Dr. Huncharek and Dr. Muscat, would be considered</p> <p>21 or groomed for being experts in litigation?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: That's not --</p> <p>24 MR. LOCKE: Objection. Did you mean to</p> <p>25 say "these witnesses"?</p>
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<p>1 to interrogatories said it cost about \$50,000.</p> <p>2 A I think that's correct, yeah.</p> <p>3 Q Okay. Did PCPC pay that or did J&J?</p> <p>4 A I believe we did.</p> <p>5 Q Okay. "We" meaning PCPC?</p> <p>6 A I'm sorry. PCPC.</p> <p>7 Q On behalf of the talc industry?</p> <p>8 A Yes.</p> <p>9 Q And one of the things that the</p> <p>10 Meta-Analysis Research Group identifies in the</p> <p>11 first paragraph that they do is they assist major</p> <p>12 pharmaceutical companies and other clients in,</p> <p>13 quote, deciphering often complex, seemingly</p> <p>14 contradictory, data using rigorous meta-analysis</p> <p>15 methods.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Do you see on the next page that it also</p> <p>19 provides medical and legal consulting in</p> <p>20 litigation?</p> <p>21 A That's what it says, yes.</p> <p>22 Q The expert witnesses. Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Do you know that both Dr. Huncharek and</p> <p>25 Dr. Muscat became expert witnesses in talc</p>	<p>1 MR. TISI: These -- yes, these doctors.</p> <p>2 THE WITNESS: We hired them for their</p> <p>3 epidemiological expertise, and they're -- they</p> <p>4 were not always favorable to us. I mean they</p> <p>5 also -- Dr. Huncharek published on hair dyes, and</p> <p>6 it was -- it was not favorable. So we -- we</p> <p>7 consider them to be fair, and their scientist</p> <p>8 arguments would stand.</p> <p>9 BY MR. TISI:</p> <p>10 Q Okay. Had you ever heard discussed --</p> <p>11 now I'm asking you as Linda Loretz -- had you ever</p> <p>12 discussed that if this case went into litigation</p> <p>13 that Drs. Huncharek and Muscat would be</p> <p>14 consultants or experts?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. TISI:</p> <p>18 Q Okay. Do you know that Meta-Analysis</p> <p>19 Research Group went out of business shortly after</p> <p>20 this --</p> <p>21 A I don't know. I did not know that.</p> <p>22 Q Do you know that they became paid</p> <p>23 litigation experts in 2010?</p> <p>24 A No.</p> <p>25 Q Now, are you aware that in 2011, after</p>

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<p>1 the filing of this report to PCPC, that they took</p> <p>2 their analysis that was paid for by PCPC and then</p> <p>3 made some modifications, but for the most part,</p> <p>4 published it as it was in the -- in the</p> <p>5 literature?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm -- I think I'm aware</p> <p>8 that there was a publication, but, no, I did not</p> <p>9 know that was happening until after the fact -- we</p> <p>10 did not know that that was happening until after</p> <p>11 the fact.</p> <p>12 (Exhibit No. 45 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. TISI:</p> <p>15 Q I'm going to show you what I've had</p> <p>16 marked as Exhibit No. 45.</p> <p>17 And this is a --</p> <p>18 (Phone interruption.)</p> <p>19 BY MR. TISI:</p> <p>20 Q This is an article that I will represent</p> <p>21 to you is very close to, if not identical in many</p> <p>22 paragraphs, to the report that was filed on behalf</p> <p>23 of PCPC. Have you seen this before?</p> <p>24 A I've -- yes.</p> <p>25 Q It was published in 2011. Correct?</p>	<p>1 talking about before.</p> <p>2 And it's on page 3 of the report,</p> <p>3 page 6 -- 6 of 9 of the letter. Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Okay. The Introduction says: "On</p> <p>6 May 13th, 2008, Samuel Epstein, MD, chairman of</p> <p>7 the Cancer Prevention Coalition, submitted a</p> <p>8 Citizen's Petition to the Commissioner of the Food</p> <p>9 and Drug Administration seeking placement of a</p> <p>10 cancer warning label on talc products. The</p> <p>11 petition requests the Commissioner of the Food and</p> <p>12 Drug require that all talcum powders bear labels</p> <p>13 with warnings such as 'Frequent application of</p> <p>14 talcum powder in the female genital area</p> <p>15 substantially increases the risk of ovarian</p> <p>16 cancer.'"</p> <p>17 Did I read that correctly?</p> <p>18 A That's what it says.</p> <p>19 Q Okay. The second paragraph -- so that</p> <p>20 just -- and that's true, that that's -- that</p> <p>21 paragraph is true, that's what Epstein did.</p> <p>22 A I would say yes.</p> <p>23 Q Okay. Second paragraph is -- is your</p> <p>24 response or the summary of your response.</p> <p>25 "Given the multiple implications of such</p>
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<p>1 A Accepted April 2011, so -- yes.</p> <p>2 Q Do you know -- do you know that there</p> <p>3 was a -- actually a proposal to -- made to Imerys</p> <p>4 that -- to turn this paper, "this" meaning the</p> <p>5 report that was submitted by PCPC in July of 2009,</p> <p>6 into a publication?</p> <p>7 A No. We were not involved.</p> <p>8 Q Okay. If you look at the back of the</p> <p>9 article, do you know -- does it acknowledge PCPC</p> <p>10 as having paid for this report?</p> <p>11 A No.</p> <p>12 Q Is there anything in that acknowledgment</p> <p>13 that would indicate that at the time that this</p> <p>14 article was published that they were paid</p> <p>15 litigation experts for the lawyers representing</p> <p>16 Johnson & Johnson?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: No, not any</p> <p>19 acknowledgments.</p> <p>20 BY MR. TISI:</p> <p>21 Q So let's put this on our timeline here,</p> <p>22 2011. And I'll put "H&M publication, 2011."</p> <p>23 Now, let's go back to the report that</p> <p>24 was filed with the FDA. And I would like to go</p> <p>25 back to the Introduction section that we started</p>	<p>1 warning labels, the Personal Care Products Council</p> <p>2 sought an evaluation of the validity of the</p> <p>3 scientific facts underlying this request. The</p> <p>4 Meta-Analysis Research Group was retained to</p> <p>5 provide an independent review of the relevant</p> <p>6 data. Below are the findings of that review."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q I'm curious about the statement saying</p> <p>10 "the multiple implications of such warning</p> <p>11 labels." Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Can you tell us on behalf of the PCPC</p> <p>14 what the multiple implications of the warning</p> <p>15 labels are that you were referring to?</p> <p>16 MR. LOCKE: Objection. Obviously this</p> <p>17 was written by doctors --</p> <p>18 MR. TISI: I'm -- I'm -- I am --</p> <p>19 BY MR. TISI:</p> <p>20 Q What are the multiple implications that</p> <p>21 were being considered there?</p> <p>22 A Again, this -- this was written not by</p> <p>23 us. I mean, I think it's pretty obvious that that</p> <p>24 would have -- could have an impact -- I mean,</p> <p>25 again, we didn't think a label was -- should be</p>

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<p>1 required because we -- because of the science</p> <p>2 behind it we believe was not supported, but</p> <p>3 obviously would have an impact on -- on the</p> <p>4 product if -- if it were.</p> <p>5 Q Okay. The "impact on the product," what</p> <p>6 do you mean?</p> <p>7 A Well, we -- we -- I mean it --</p> <p>8 Q Well, let me ask --</p> <p>9 A We don't think it should have a warning</p> <p>10 if it's -- if we don't believe that it --</p> <p>11 Q Let me ask you some -- I didn't mean to</p> <p>12 interrupt you. Go finish, if you'd like.</p> <p>13 A No, just that if -- because we didn't --</p> <p>14 we don't believe that the science shows causation,</p> <p>15 we just did not believe you have a warning to</p> <p>16 scare people off of something if it's not real.</p> <p>17 Q Okay. So let me ask you -- I understand</p> <p>18 your position that you did not think the evidence</p> <p>19 supported a causal inference.</p> <p>20 Putting that issue aside, the company</p> <p>21 through its consultants assert -- make an</p> <p>22 assertion that warnings labels would have</p> <p>23 implications. Do you see that?</p> <p>24 A Yes.</p> <p>25 Q And not only implications, have multiple</p>	<p>1 than stating what Dr. Epstein did, the first --</p> <p>2 first sentence of that paragraph, you say that</p> <p>3 the -- that your consultants on your behalf say:</p> <p>4 "Given the multiple implications on such a warning</p> <p>5 label, the Personal Care Products Council sought</p> <p>6 an evaluation of the validity of the scientific</p> <p>7 facts underlying this request."</p> <p>8 So this statement is the predicate of</p> <p>9 why the PCPC got this report in the first place,</p> <p>10 correct?</p> <p>11 A Sure.</p> <p>12 Q Okay. And so the predicate was that</p> <p>13 there were multiple implications of that warning,</p> <p>14 of a warning, should it be required. And this, to</p> <p>15 be clear, is a request that warning labels be</p> <p>16 mandated. Correct?</p> <p>17 A Correct.</p> <p>18 Q And you were aware that companies can</p> <p>19 and in fact have voluntarily added a warning,</p> <p>20 correct?</p> <p>21 A Sure.</p> <p>22 Q Okay. So this is different than that.</p> <p>23 I mean companies can voluntarily add a warning.</p> <p>24 A Yes.</p> <p>25 Q But this is in the absence of a company</p>
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<p>1 implications. Correct?</p> <p>2 A That's what it says.</p> <p>3 Q Okay. And I'm curious as to what those</p> <p>4 implications were from your perspective, from the</p> <p>5 PCPC's perspective.</p> <p>6 Was there concern ever expressed that</p> <p>7 adding a warning would have an impact on the</p> <p>8 members of the PCPC? You've heard that, correct?</p> <p>9 A Yeah, again --</p> <p>10 Q Okay.</p> <p>11 A -- I think the reason that -- we would</p> <p>12 not want that, though, is because we do believe</p> <p>13 the science doesn't support the need for a</p> <p>14 warning.</p> <p>15 Q I -- I understand.</p> <p>16 A It has to be part of the context of my</p> <p>17 answer.</p> <p>18 Q I'm going -- Doctor, I'm going to ask</p> <p>19 you a lot about this document, okay? And we're</p> <p>20 going to go through it probably more than you want</p> <p>21 to. Okay?</p> <p>22 A Sure.</p> <p>23 Q But before we do, I want to understand</p> <p>24 the context in which it's written. Okay?</p> <p>25 And in the very first paragraph, other</p>	<p>1 voluntarily adding a warning, they're going right</p> <p>2 to the FDA and saying, The companies are not doing</p> <p>3 it, and we're going to ask you -- require you to</p> <p>4 do it. Correct?</p> <p>5 A Yes.</p> <p>6 Q All right. And the PCPC, as a predicate</p> <p>7 for opposing that requirement, laid out that there</p> <p>8 are multiple implications to requiring that</p> <p>9 warning. Correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: That's what it says, yes.</p> <p>12 BY MR. TISI:</p> <p>13 Q All right. And the multiple -- the</p> <p>14 implications are -- I mean let's -- let's -- I'm</p> <p>15 going to lay out some for you and ask you whether</p> <p>16 they were things that were discussed at the time.</p> <p>17 Was one of the implications that it</p> <p>18 would affect the commercial interests of the</p> <p>19 members of the PCPC?</p> <p>20 A With the context being that we did not</p> <p>21 believe that it truly had this risk, you do not</p> <p>22 want to affect sales and so forth without --</p> <p>23 Q Okay.</p> <p>24 A -- if it's -- if there's no reason for</p> <p>25 having a warning.</p>

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<p>1 Q Understood. We're going to talk about 2 the reasons. 3 A Okay. 4 Q I just want to know the implications. 5 A Okay. 6 Q Right? 7 A Yep. 8 Q So the first implication would be -- and 9 I will write it on here, "Implications of 10 warnings. 1. Sales." 11 Had you ever heard in the context -- 12 since there were multiple implications, had you 13 ever heard in the context that providing a warning 14 after this being in the medical literature for 25 15 years would open up members to the potential -- 16 for the reason why we're all here today, potential 17 lawsuits? 18 A No. 19 Q You never heard that? 20 MR. LOCKE: Objection. 21 THE WITNESS: We never talked about 22 that. 23 BY MR. TISI: 24 Q Never talked about that at all? 25 A No.</p>	<p>1 A Yes. 2 Q All right. And so what I'm trying to 3 explore with you is what potential -- and I'll put 4 it right on the table -- what potential biases 5 might have been present when this opposition was 6 sent to the FDA. Okay? 7 A Okay. 8 Q All right. So we'll talk about the 9 science and we'll talk -- but before we talk about 10 the science, I want to talk about the prism 11 through which you looked at the science. Okay? 12 A Okay. 13 Q And one of the things that was a concern 14 to the members, we talked about sales. Had you 15 ever heard of any concerns about litigation? 16 A I can tell you that was not something we 17 ever discussed. 18 Q Okay. Is it something you understood? 19 A Sure. At some level, of course. 20 Q Okay. And if sales -- people stop 21 selling talc, and use corn starch, for example, 22 instead of talc, that may impact the membership of 23 the PCPC as well, correct? 24 MR. LOCKE: Objection. 25 THE WITNESS: I mean I didn't -- no,</p>
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<p>1 Q You never heard that -- that adding a 2 warning might -- might raise -- might cause people 3 to bring claims such as this? 4 A We just talked about the science. 5 Q I'm not -- I'm going to talk about the 6 science in a moment, okay? We're going to get to 7 the science. 8 But oftentimes -- you're aware as a 9 scientist that oftentimes the reason why we do 10 disclosures in medical and scientific literature 11 is so that people could understand the biases or 12 potential biases or potential conflicts of 13 interest that the authors might have, correct? 14 MR. LOCKE: Objection. 15 THE WITNESS: Say it one more time. 16 BY MR. TISI: 17 Q Medical articles oftentimes come with 18 disclosures about affiliations, conflicts of 19 interest. 20 A Sure. 21 Q And the reason why we do that -- 22 A Yes. 23 Q -- is so that people reading those 24 articles can understand why -- perhaps biases that 25 the authors bring to the table, correct?</p>	<p>1 that's not -- that's not what I thought. I mean 2 to me that -- that wouldn't really make sense. I 3 mean if you have a product that's corn starch 4 instead of talc, it's still a product. So I don't 5 think that's really relevant. 6 BY MR. TISI: 7 Q Right. But Imerys -- Imerys doesn't 8 manufacture corn starch, do they? 9 A No, but I -- I guess -- 10 Q So they would fall out of the -- they 11 might fall out of the PCPC, correct? 12 A I don't -- no, I never thought about, 13 and I don't think -- I never ever heard anybody 14 mention that. 15 Q Any of the -- any other -- since there 16 were multiple implications, any other implications 17 you could think of as to why you sought to get 18 this independent evaluation to submit to the FDA 19 in opposition to letting women know there was a 20 potential for ovarian cancer based upon the 21 literature? 22 A I think given -- 23 MR. LOCKE: Objection. 24 THE WITNESS: -- given our position that 25 we don't believe there is a causal role, I don't</p>

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<p>1 think you want to put warnings on products</p> <p>2 suggesting that there's some harm when there's</p> <p>3 not, scaring people or having people think that</p> <p>4 some harm that they've experienced has something</p> <p>5 to do with this when in fact it doesn't.</p> <p>6 BY MR. TISI:</p> <p>7 Q So you were concerned about scaring</p> <p>8 people. With baby powder.</p> <p>9 A Yeah, a warning is --</p> <p>10 Q Okay.</p> <p>11 A -- is a scary thing, sure.</p> <p>12 Q And if -- if a woman was told that --</p> <p>13 that talcum powder products, and we talked about</p> <p>14 this for 25 years that was being discussed in the</p> <p>15 medical literature, if they were concerned by</p> <p>16 that, there were other alternatives on -- on the</p> <p>17 shelves, right? There was corn starch, correct?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 THE WITNESS: Yeah, again, the context</p> <p>20 to me is that if we did not believe that it was a</p> <p>21 real risk, that's where you don't want to warn.</p> <p>22 BY MR. TISI:</p> <p>23 Q And -- well, but that's my reason why I</p> <p>24 asked you before what the standard was. If the</p> <p>25 standard was -- is the standard for warning that</p>	<p>1 literature on ovarian cancer?</p> <p>2 A No.</p> <p>3 Q Okay. Since 2009, did PCPC ever discuss</p> <p>4 with its members whether or not its members should</p> <p>5 voluntarily add an informational label or warning</p> <p>6 label about perineal dusting with talcum powder</p> <p>7 products?</p> <p>8 A No.</p> <p>9 Q Do you know that some talcum powder</p> <p>10 products have in fact voluntarily added warnings</p> <p>11 or information about the potential risk of talcum</p> <p>12 powder products?</p> <p>13 A I didn't know that, but --</p> <p>14 Q Are you familiar with a company called</p> <p>15 Belk -- Belcam Inc.?</p> <p>16 A No.</p> <p>17 Q Greenbriar?</p> <p>18 A No.</p> <p>19 Q Assured?</p> <p>20 A No.</p> <p>21 Q Okay. There are members -- there are</p> <p>22 people who actually manufacture talcum powder</p> <p>23 products that are not members of the PCPC,</p> <p>24 correct?</p> <p>25 A I would assume so.</p>
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<p>1 you have to be convinced of a real risk?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q Or that there may be a risk. What is</p> <p>5 the standard for a warning, and did you even know</p> <p>6 at the time you sent this to the FDA?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Again, I would just say</p> <p>9 there were people within -- within PCPC who know a</p> <p>10 lot more on this topic than I do, and --</p> <p>11 BY MR. TISI:</p> <p>12 Q Did they --</p> <p>13 A -- the awareness of --</p> <p>14 Q Did you send this to the lawyers at the</p> <p>15 PCPC, this letter?</p> <p>16 A This -- I can't recall exactly who read</p> <p>17 it, but I can tell you that certainly, you know,</p> <p>18 everything that -- when things like this happen,</p> <p>19 they are -- it's known without the associate --</p> <p>20 throughout the association at the higher levels.</p> <p>21 Q Now, prior to this time, did the PCPC</p> <p>22 ever discuss either with the FDA or whether or not</p> <p>23 it's members should voluntary add a warning or</p> <p>24 precaution or informational statement about</p> <p>25 cosmetic talc and the current state of the</p>	<p>1 Q Are you aware that some manufacturers</p> <p>2 have stopped selling talcum powder products</p> <p>3 altogether and use -- and just have decided to use</p> <p>4 corn starch, correct? Do you know that?</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: I guess I don't know that,</p> <p>7 but I could find it plausible.</p> <p>8 BY MR. TISI:</p> <p>9 Q Okay. Let's get back to the response to</p> <p>10 the Citizen's Petition.</p> <p>11 Do you know -- we mentioned before, and</p> <p>12 I just want to make sure that we understand, this</p> <p>13 PCPC response was actually commissioned by</p> <p>14 Johnson & Johnson in 2008, correct?</p> <p>15 A I believe they started the process</p> <p>16 rolling, yes.</p> <p>17 Q Well, it's more than starting the</p> <p>18 process. The report was actually written for J&J.</p> <p>19 A I -- I -- yeah, I think when we got it,</p> <p>20 it was -- it was --</p> <p>21 Q It was pretty --</p> <p>22 A The report had been -- was in pretty</p> <p>23 good shape, yes.</p> <p>24 Q It was -- it was pretty much written by</p> <p>25 the time you got it.</p>

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<p>1 A I believe so, yes.</p> <p>2 Q Did you understand this was a</p> <p>3 collaborative response by J&J and Imerys</p> <p>4 primarily?</p> <p>5 A I'm not sure that I did.</p> <p>6 Q Did other manufacturers -- there are</p> <p>7 other manufacturers of talcum powder products,</p> <p>8 correct?</p> <p>9 A There are certainly other people on our</p> <p>10 Talc Task Force or the people with an interest in</p> <p>11 talc.</p> <p>12 Q Do you know --</p> <p>13 A Other companies, rather.</p> <p>14 Q Do you know that -- whether they had</p> <p>15 input into this PCPC response, or was it primarily</p> <p>16 a J&J, with the assistance of Imerys, production?</p> <p>17 A I believe we would have sent it to other</p> <p>18 people with interest. I mean, that's our normal</p> <p>19 process.</p> <p>20 Q Do you know whether that was happening?</p> <p>21 A I mean, I don't, but that would be our</p> <p>22 normal process.</p> <p>23 (Exhibit No. 46 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. TISI:</p>	<p>1 submission, this was submitted by a PCPC employee</p> <p>2 by the name of John Bailey. I want to talk to you</p> <p>3 a little bit about who John Bailey is and was.</p> <p>4 A Okay.</p> <p>5 Q Who is John Bailey?</p> <p>6 A He -- at the time of this, he was the</p> <p>7 vice president of science -- the science</p> <p>8 department. He was my boss -- or, rather, the</p> <p>9 executive vice president of the science department</p> <p>10 at PCPC.</p> <p>11 Q Okay. He previously worked at the FDA,</p> <p>12 didn't he?</p> <p>13 A He did.</p> <p>14 Q And in fact, he was hired directly from</p> <p>15 the FDA by PCPC.</p> <p>16 A That's correct.</p> <p>17 Q Okay. And at the time that he left the</p> <p>18 FDA in December of 2001, he was with what</p> <p>19 division, do you know?</p> <p>20 A Office of Cosmetics and Colors.</p> <p>21 Q And at that time in 2001, the NTP had</p> <p>22 actually deferred consideration of talc as a -- a</p> <p>23 carcinogen, correct?</p> <p>24 A Yes.</p> <p>25 Q Okay. And when we say "deferred," I</p>
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<p>1 Q So I'm going to show you what I've had</p> <p>2 marked as Exhibit No. 46. And it's a date -- and</p> <p>3 you're not on this, but I'm doing this just to</p> <p>4 kind of see if I can hone in the time frame.</p> <p>5 This is an e-mail from Kathleen Wille.</p> <p>6 Do you know who Kathleen Wille is?</p> <p>7 A Yes.</p> <p>8 Q Okay. She works with J&J?</p> <p>9 A Yeah, I'm not sure if she's still there,</p> <p>10 but yes.</p> <p>11 Q And it's entitled "Response to Citizens</p> <p>12 Petition on Talc, Latest Review of the Data," and</p> <p>13 its attachment is a J&J report. Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Okay. And it says: "This is the report</p> <p>16 that we will -- that we will submit to FDA in</p> <p>17 response to the Citizen's Petition. We originally</p> <p>18 commissioned the work; however, the trade</p> <p>19 association will be the submitter."</p> <p>20 Is that an accurate statement of what</p> <p>21 happened?</p> <p>22 A I don't know, but I'm -- well, yes, they</p> <p>23 commissioned it, and we -- we submitted it, that's</p> <p>24 correct, yes.</p> <p>25 Q Okay. Now, going back to the actual FDA</p>	<p>1 want to stop and pause on that for a moment</p> <p>2 because it -- I just want to make absolutely</p> <p>3 clear, and we'll talk about this in a moment.</p> <p>4 They deferred the question, they did not</p> <p>5 decide the question.</p> <p>6 A That's what -- that was under the</p> <p>7 official, what they did, yes.</p> <p>8 Q Okay. And so in that context, PCPC just</p> <p>9 immediately following that -- well, when it was</p> <p>10 deferred, there was an understanding that the</p> <p>11 issue might come up again.</p> <p>12 A Yes.</p> <p>13 Q And in fact, it did come up again,</p> <p>14 correct?</p> <p>15 A Kind of.</p> <p>16 Q It came up with IARC?</p> <p>17 A Oh, it came up in other contexts, sure.</p> <p>18 Q Came up in IARC?</p> <p>19 A Yes.</p> <p>20 Q This issue -- and again, it bears</p> <p>21 repeating because I want to make sure -- at all</p> <p>22 times on this continuum, on this timeline, the</p> <p>23 issue of talcum powder products causing or</p> <p>24 contributing to ovarian cancer was an active</p> <p>25 debate. Sometimes more active, sometimes less</p>

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<p style="text-align: right;">Page 456</p> <p>1 active. But this was something that was a concern</p> <p>2 to your members throughout the entire time of this</p> <p>3 timeline.</p> <p>4 MR. LOCKE: Objection. Form.</p> <p>5 THE WITNESS: It was being talked about</p> <p>6 by someone.</p> <p>7 BY MR. TISI:</p> <p>8 Q Right. And so in the context of hiring</p> <p>9 Dr. Bailey, he was hired by -- by PCPC from the</p> <p>10 division of the FDA, the Office of colors --</p> <p>11 Cosmetics and Colors --</p> <p>12 A Cosmetics and Colors.</p> <p>13 Q -- that would interact with the cosmetic</p> <p>14 industry on talc issues, correct?</p> <p>15 A As well as many other issues, yes.</p> <p>16 Q Right. And the person who took over was</p> <p>17 a Dr. Katz?</p> <p>18 A Yes.</p> <p>19 Q And Dr. Katz worked for Dr. -- had</p> <p>20 worked for Dr. Bailey at the time, correct?</p> <p>21 A I actually don't know that.</p> <p>22 Q All right. And he was the director of</p> <p>23 that office, correct?</p> <p>24 A That's correct, yes.</p> <p>25 Q And when he left FDA in December of</p>	<p style="text-align: right;">Page 458</p> <p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. TISI:</p> <p>4 Q And he was -- he was going to the very</p> <p>5 same office that he ran, correct?</p> <p>6 A In -- at that meeting there was more</p> <p>7 than just the Office of Cosmetics and Colors.</p> <p>8 Q Well, we're going to talk about that.</p> <p>9 But -- but the people who were -- the vast</p> <p>10 majority of the people at that FDA employees were</p> <p>11 people from the Office of Cosmetics and Colors.</p> <p>12 A I'm not sure about the vast majority,</p> <p>13 but certainly there were people there, and that --</p> <p>14 that may well be right.</p> <p>15 Q Including Dr. Katz.</p> <p>16 A Dr. Katz was there.</p> <p>17 Q And I want to put this on a timeline in</p> <p>18 a moment, but Dr. Bailey left PCPC after this</p> <p>19 petition -- this opposition was -- was correct,</p> <p>20 filed?</p> <p>21 A He's -- he left, yes. I'm not sure</p> <p>22 exactly -- the exact year, but yes.</p> <p>23 Q About 2011 -- 2010, 2011?</p> <p>24 A That sounds roughly right.</p> <p>25 Q Okay. So before we discuss the science</p>
<p style="text-align: right;">Page 457</p> <p>1 2001, he became -- he was hired in January of 2002</p> <p>2 by PCPC.</p> <p>3 A I couldn't confirm those dates, but --</p> <p>4 Q Okay. And he interacted with the -- and</p> <p>5 we're going to talk about this -- he's writing the</p> <p>6 response to this petition that would go to the</p> <p>7 very same division, the Office of Cosmetics and</p> <p>8 Colors, that actually he ran while he was at the</p> <p>9 FDA.</p> <p>10 A Yes, although I think the heart of our</p> <p>11 submission is the scientific analysis.</p> <p>12 Q Right.</p> <p>13 A Not the cover letter, but the --</p> <p>14 Q But the cover letter -- the cover</p> <p>15 letter -- well, let's -- let's call it what it is.</p> <p>16 He actually sent the letter and he actually met</p> <p>17 with you -- with you at the Office of Cosmetics</p> <p>18 and Colors before this was filed in July.</p> <p>19 A Oh --</p> <p>20 Q There was a meeting at the FDA --</p> <p>21 A Correct.</p> <p>22 Q -- where you and Dr. Bailey went to the</p> <p>23 FDA, previewed this document that Dr. Huncharek</p> <p>24 and Muscat had provided, and then filed it</p> <p>25 subsequently, correct?</p>	<p style="text-align: right;">Page 459</p> <p>1 that was provided by PCPC, and I told you we would</p> <p>2 do that, let's see if we can pause here and put</p> <p>3 together -- fill out our timeline a little bit</p> <p>4 about the context of everything that happened.</p> <p>5 First of all, we talked about the fact</p> <p>6 that talcum powder products may cause or</p> <p>7 contribute to ovarian cancer was a concern since</p> <p>8 the early 1980s and it was debated throughout the</p> <p>9 entire time, correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: There were ongoing</p> <p>12 happenings related to that topic, yes.</p> <p>13 BY MR. TISI:</p> <p>14 Q Okay. Can we say -- can we use the word</p> <p>15 "consistent" here? It was a consistent topic of</p> <p>16 discussion in the medical and scientific</p> <p>17 community?</p> <p>18 A There were a number of publications, but</p> <p>19 I mean not every --</p> <p>20 Q I mean I'm not saying you woke up in the</p> <p>21 morning and discussed it. I'm saying that within</p> <p>22 this topic was a topic that was -- it wasn't just</p> <p>23 a flash in the pan. It was something that was</p> <p>24 discussed over the -- over this 25 years</p> <p>25 represented by this chart.</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Again, with the</p> <p>3 understanding that there were publications, but</p> <p>4 not all of them showed any sort of association --</p> <p>5 BY MR. TISI:</p> <p>6 Q And some did.</p> <p>7 A -- and some did and some -- and some did</p> <p>8 and some -- but there were a lot of weaknesses in</p> <p>9 the --</p> <p>10 Q Well, I mean, my question is that was an</p> <p>11 active debate, correct, what those studies meant?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: I guess that's fair to</p> <p>14 say.</p> <p>15 BY MR. TISI:</p> <p>16 Q Okay. So can we write "Active debate</p> <p>17 between scientists." Is that okay?</p> <p>18 A Okay.</p> <p>19 MR. LOCKE: Objection.</p> <p>20 BY MR. TISI:</p> <p>21 Q Is that accurate?</p> <p>22 MR. LOCKE: Same objection.</p> <p>23 THE WITNESS: I -- I suppose.</p> <p>24 BY MR. TISI:</p> <p>25 Q Okay. All right. So, for example, some</p>	<p>1 Q I'll show you a document, if I -- if I</p> <p>2 could, but that was an issue that PCPC knew and</p> <p>3 understood that the FDA was concerned about.</p> <p>4 A They --</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: They had an interest and a</p> <p>7 concern with, okay.</p> <p>8 (Exhibit No. 47 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. TISI:</p> <p>11 Q I'm going to show you a document that</p> <p>12 I've marked as Exhibit No. 47, and it's draft</p> <p>13 minutes of the CTFA talc force.</p> <p>14 And we're going to talk about this</p> <p>15 later, but this is Exhibit No. -- I said 47?</p> <p>16 MR. LOCKE: Yes.</p> <p>17 BY MR. TISI:</p> <p>18 Q Now you see why I used 1994 is on my --</p> <p>19 A Mm-hmm.</p> <p>20 Q -- on my timeline here.</p> <p>21 A Yes, right, but the -- the workshop,</p> <p>22 yes.</p> <p>23 Q Okay. And this was a workshop dated</p> <p>24 April 12th, 1994, correct?</p> <p>25 A Yes.</p>
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<p>1 like Dr. Cramer or Dr. Epstein on one hand thought</p> <p>2 there was -- that there was evidence of a causal</p> <p>3 association, and some people like Huncharek and</p> <p>4 Muscat thought there was not.</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: There were different</p> <p>7 opinions, yes.</p> <p>8 BY MR. TISI:</p> <p>9 Q Based on the same literature.</p> <p>10 A Yes.</p> <p>11 Q Okay. Now, another point before we put</p> <p>12 things on a timeline, the PCPC knew that the FDA</p> <p>13 had been concerned about the issue since at least</p> <p>14 the 1990s, correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: They responded before,</p> <p>17 yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q But they were concerned about the issue.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I -- I guess, yes. I</p> <p>22 mean --</p> <p>23 BY MR. TISI:</p> <p>24 Q Well, I mean don't guess.</p> <p>25 A Well --</p>	<p>1 Q Okay. It's actually written by a</p> <p>2 Stephen Gettings?</p> <p>3 A Yes.</p> <p>4 Q Who is Dr. Gettings?</p> <p>5 A Dr. Gettings was my predecessor.</p> <p>6 Q All right. And this is a report of a</p> <p>7 meeting amongst -- this is the Talc Interested</p> <p>8 Party Task Force. Among other things, Johnson &</p> <p>9 Johnson and the predecessor for Luzenac were</p> <p>10 there.</p> <p>11 A Yes.</p> <p>12 Q Okay. And I'm going to come back to</p> <p>13 this in a minute when I talk about the second area</p> <p>14 which we talked about, which is studies.</p> <p>15 A Okay.</p> <p>16 Q But -- but I'm just concerned with point</p> <p>17 number 1. It says: "It was noted that the FDA</p> <p>18 still appears to be concerned with the issue of</p> <p>19 ovarian cancer as evidenced by their contact with</p> <p>20 the NTP."</p> <p>21 Do you see that?</p> <p>22 A Yes.</p> <p>23 Q Okay. So at least as of this date,</p> <p>24 you're aware that the FDA had some concerns about</p> <p>25 talc and ovarian cancer.</p>

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<p>1 A Okay.</p> <p>2 Q Is that accurate?</p> <p>3 A I'm going to say yes.</p> <p>4 Q Okay. So let's put this on our timeline</p> <p>5 here, 1994. And this would be "Task force with</p> <p>6 the FDA, concern about ovarian cancer."</p> <p>7 By the way, ovarian cancer, this is not</p> <p>8 a trivial issue, is it?</p> <p>9 A No.</p> <p>10 Q And ovarian cancer is a -- ovarian</p> <p>11 cancer is -- affects 20 -- 20,000 -- 20,000 women</p> <p>12 a year get diagnosed with ovarian cancer, correct?</p> <p>13 A Yes.</p> <p>14 Q It has a high mortality rate. Correct?</p> <p>15 A Yes. Yes.</p> <p>16 Q Very serious.</p> <p>17 A Absolutely.</p> <p>18 Q And by contrast, baby powder is not a</p> <p>19 necessary pharmaceutical, correct?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 BY MR. TISI:</p> <p>22 Q Is it fair to say you can live without</p> <p>23 baby powder?</p> <p>24 MR. LOCKE: Objection. Beyond the</p> <p>25 scope.</p>	<p>1 was talking before, people can look at the same</p> <p>2 evidence and come to different conclusions,</p> <p>3 correct?</p> <p>4 A I think there was some different</p> <p>5 evidence. I think it really was bringing forth</p> <p>6 some things that were mistaken in the draft</p> <p>7 report, particularly regarding mineralogy and --</p> <p>8 and so forth.</p> <p>9 Q Right. And one of the things -- one of</p> <p>10 the things that was the basis of the deference is</p> <p>11 that there was not a clear understanding of what</p> <p>12 at that time was in talcum powder products.</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I think there wasn't</p> <p>15 also -- there was not a clear definition of -- in</p> <p>16 fact, when they wanted to look at it again or</p> <p>17 considered looking at it again, they changed the</p> <p>18 name of what they were going to look at, because</p> <p>19 it was hard -- it was not clear what they were</p> <p>20 trying to look at, and that was something that got</p> <p>21 discussion at the NTP, and I think that made a</p> <p>22 difference and explains part of why there were</p> <p>23 different conclusions from the first two review</p> <p>24 groups.</p> <p>25 BY MR. TISI:</p>
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<p>1 BY MR. TISI:</p> <p>2 Q Talcum powder.</p> <p>3 A Yes.</p> <p>4 Q Now, in 2000, we have the NTP 10th</p> <p>5 Report on Carcinogen, and we talk about the word</p> <p>6 "defer."</p> <p>7 And I want to write that clearly because</p> <p>8 my handwriting is terrible.</p> <p>9 Okay. And they deferred the question.</p> <p>10 A They did. They did vote. They voted,</p> <p>11 but then they deferred.</p> <p>12 Q Right.</p> <p>13 A But they voted against listing seven to</p> <p>14 three, but then they deferred.</p> <p>15 Q Well, there were different -- okay.</p> <p>16 Since you raised that, let's -- you knew this was</p> <p>17 going to happen. I was not going to get into it,</p> <p>18 but let's -- let's -- there were three committees</p> <p>19 that looked at the -- looked at this, correct?</p> <p>20 A Mm-hmm.</p> <p>21 Q Two of them voted in favor of listing.</p> <p>22 A That's correct.</p> <p>23 Q And one voted against, correct?</p> <p>24 A Yes.</p> <p>25 Q Okay. And that's kind of the issue I</p>	<p>1 Q All right. And the third review group</p> <p>2 was not unanimous, was it?</p> <p>3 A They -- they did do a vote. I -- I've</p> <p>4 been calling it seven to three against listing,</p> <p>5 and then they -- and then they decided to defer</p> <p>6 because there were --</p> <p>7 Q And again, that's -- that's -- that's</p> <p>8 the kind of example that I'm talking about of even</p> <p>9 if it was seven to three against listing talc,</p> <p>10 there were three people who thought that it should</p> <p>11 be listed, correct?</p> <p>12 A Sure.</p> <p>13 Q So this is -- this is kind of</p> <p>14 crystalizing what we've been talking about, which</p> <p>15 is different scientists can look at the evidence</p> <p>16 and reach different conclusions, true?</p> <p>17 A Yes.</p> <p>18 Q And in fact, did reach different</p> <p>19 conclusions, correct?</p> <p>20 A Yes.</p> <p>21 Q All right. Okay. So we put that on our</p> <p>22 timeline here.</p> <p>23 Now, prior to that last discussion --</p> <p>24 prior to that deferral, that last meeting, the</p> <p>25 PCPC actually drafted or commissioned a report,</p>

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<p>1 correct?</p> <p>2 A You mean -- to be submitted to the</p> <p>3 NTP --</p> <p>4 Q Yes.</p> <p>5 A -- for the meeting? Yes.</p> <p>6 Q Yeah. And I'm just going to identify</p> <p>7 it because I don't want to go into it, but -- but</p> <p>8 here is a copy of the actual letter, Exhibit</p> <p>9 No. 48.</p> <p>10 (Exhibit No. 48 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. TISI:</p> <p>13 Q And one of the things that the -- and</p> <p>14 this would have been -- we'll put it on our</p> <p>15 timeline, this would have been December of 2000</p> <p>16 and -- 2000. So we will put "PCPC CFTA</p> <p>17 submission."</p> <p>18 And the only reason I bring this up is</p> <p>19 Dr. Muscat is the very same doctor who --</p> <p>20 Dr. Muscat wrote a report that was submitted to</p> <p>21 NTP, correct?</p> <p>22 A That's correct.</p> <p>23 Q All right. And it's the very same</p> <p>24 Dr. Muscat that wrote the report with -- which was</p> <p>25 a Citizen's Petition with Dr. Huncharek.</p>	<p>1 that at the actual meeting, but I -- that's what I</p> <p>2 recall. I think we walked away knowing where they</p> <p>3 came out, but I -- I could be wrong on that, but,</p> <p>4 yes, it was confirmed then. Certainly.</p> <p>5 (Exhibit No. 49 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. TISI:</p> <p>8 Q Okay. And I'm going to hand you Exhibit</p> <p>9 No. 40 -- 49. And this is the Code of Federal</p> <p>10 Regulations dated 2005. But if you look at the</p> <p>11 back, the last page with a 12 Bates stamp at the</p> <p>12 end.</p> <p>13 A Okay.</p> <p>14 Q And it says the basis was the NTP</p> <p>15 deferred -- do you see that "Basis for</p> <p>16 nomination"?</p> <p>17 A Yes.</p> <p>18 Q It says: "The NTP deferred</p> <p>19 consideration of listing talc asbestiform and</p> <p>20 non-asbestiform talc in the 10th RoC because its</p> <p>21 2000 review of talc found that there's been</p> <p>22 considerable confusion over the mineral nature and</p> <p>23 consequences of talc, both containing asbestiform</p> <p>24 fibers and not containing asbestiform fibers."</p> <p>25 Do you see that?</p>
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<p>1 A It is.</p> <p>2 Q Okay. So we're going to put "Muscat"</p> <p>3 there. Okay.</p> <p>4 Now, Dr. Muscat was actually recommended</p> <p>5 to the PCPC by Johnson & Johnson, correct? Back</p> <p>6 in 2000.</p> <p>7 A I think that's correct.</p> <p>8 Q So I don't have to use a document. Is</p> <p>9 that correct? I'm happy to use the document,</p> <p>10 but --</p> <p>11 A Okay. Then I'm going to say I think --</p> <p>12 yes, I believe that's correct.</p> <p>13 Q Okay. We just cut ourselves five</p> <p>14 minutes, so --</p> <p>15 A Yea.</p> <p>16 Q All right. And just to kind of put it</p> <p>17 again on our timeline, when did the -- when did</p> <p>18 the NTP defer the issue of whether or not talc was</p> <p>19 a carcinogen?</p> <p>20 A I believe they actually did it at their</p> <p>21 actual meeting, which was in December of 2000.</p> <p>22 Q 2000. And -- you became aware of the</p> <p>23 actual deferral in the CFR? The Code of Federal</p> <p>24 Regulations actually lists it as being --</p> <p>25 A Yeah, I mean I -- I thought they said</p>	<p>1 A Yes.</p> <p>2 Q It further says: "It became evident</p> <p>3 that the literature on both forms of talc with few</p> <p>4 exceptions provide inadequate characterization of</p> <p>5 the adequate material under study," and you see --</p> <p>6 and it just continues from there.</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q Okay. And so the question at that point</p> <p>10 was deferred because there was a question as to</p> <p>11 what was cosmetic talc.</p> <p>12 A Well, I mean this is where it was</p> <p>13 withdrawn.</p> <p>14 Q No, withdrawn --</p> <p>15 A This is 2005.</p> <p>16 Q 2005. But in the basis for -- it talks</p> <p>17 about what happened in the --</p> <p>18 A Oh, the deferral that they're referring</p> <p>19 to, yes, correct.</p> <p>20 Q Okay. All right. And then in 12, in</p> <p>21 the -- it was renominated in 2004, correct?</p> <p>22 A Right.</p> <p>23 Q Right. And so I'm going to put year</p> <p>24 "2004," I'm going to put "renominated NTP." NTP.</p> <p>25 My handwriting is terrible.</p>

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<p>1 And -- but at that time it -- the IARC</p> <p>2 had also taken up the issue, correct?</p> <p>3 A I'm not sure when I learned about IARC</p> <p>4 taking up the issue, but I think they -- I mean,</p> <p>5 so I'm not sure.</p> <p>6 Q Okay. And IARC is what?</p> <p>7 A International Agency for Research on</p> <p>8 Cancer.</p> <p>9 Q Is it a reputable organization?</p> <p>10 A It's an arm of the World Health</p> <p>11 Organization.</p> <p>12 Q Is it one that in your view is one that</p> <p>13 is -- does good science?</p> <p>14 A They have -- I mean, it's --</p> <p>15 Q You may disagree with them on occasion,</p> <p>16 but do they do good science?</p> <p>17 A It's a closed process, and I think</p> <p>18 they're considered reputable. It is a very closed</p> <p>19 process.</p> <p>20 Q When you say "closed," they don't have</p> <p>21 people from industry who come in and -- and</p> <p>22 participate, correct?</p> <p>23 A Well --</p> <p>24 Q People affiliated with industry cannot</p> <p>25 sit on the panels, correct? There are limitations</p>	<p>1 possible, correct? To be.</p> <p>2 A Yes.</p> <p>3 Q Now, in 2005, you know that Dr. Muscat</p> <p>4 and Huncharek were retained by Imerys and a law</p> <p>5 firm to write a meta-analysis and a review paper</p> <p>6 on talc, correct?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: I don't think I knew that,</p> <p>9 no.</p> <p>10 MR. TISI: Okay. Let me show you what I</p> <p>11 would like to have marked as Exhibit No. 50.</p> <p>12 (Exhibit No. 50 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. TISI:</p> <p>15 Q And I'm not concerned with the top</p> <p>16 e-mail because that's not to you, but the bottom</p> <p>17 e-mail is to you, correct?</p> <p>18 A Yes.</p> <p>19 Q Okay. It's from Robert Glenn?</p> <p>20 MR. LOCKE: Let's let --</p> <p>21 MR. TISI: I'm going to. I'm just going</p> <p>22 to --</p> <p>23 MR. LOCKE: -- the witness just read it.</p> <p>24 MR. TISI: I'm going to have to -- I'm</p> <p>25 just going to direct her to what it is before we</p>
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<p>1 into who can sit, correct?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: That is true, but it's</p> <p>4 also closed in the sense basically they decide on</p> <p>5 a working group and that's the working group. So</p> <p>6 are those the best people always? I mean, I think</p> <p>7 there's that -- there's that question of -- you</p> <p>8 know, it's like any process, it's --</p> <p>9 BY MR. TISI:</p> <p>10 Q Have you ever seen an unqualified person</p> <p>11 on an IARC panel?</p> <p>12 A I -- I mean, I really can't answer that.</p> <p>13 You know.</p> <p>14 Q Okay. All right. So IARC review was in</p> <p>15 2006, correct?</p> <p>16 A Yes.</p> <p>17 Q Okay. And they considered the issue,</p> <p>18 and they found that cosmetic talc would be a</p> <p>19 possible carcinogen. They looked at the evidence,</p> <p>20 right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: They said limited</p> <p>23 evidence.</p> <p>24 BY MR. TISI:</p> <p>25 Q Okay. But they categorized it as</p>	<p>1 do it, because if she didn't get it, then I'm not</p> <p>2 going to go there.</p> <p>3 BY MR. TISI:</p> <p>4 Q This is an e-mail to you from Robert</p> <p>5 Glenn.</p> <p>6 A Okay.</p> <p>7 Q Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And it's dated August 3rd, 19 -- 2005.</p> <p>10 A Okay.</p> <p>11 Q Okay. And it's entitled "Rothman</p> <p>12 Proposal for Updating CTFA Submission on Comments</p> <p>13 to NTP." Correct?</p> <p>14 A I'm sorry, where are you?</p> <p>15 Q It's the subject matter.</p> <p>16 A Yes.</p> <p>17 Q Okay. And it's by Crowell & Moring LLP.</p> <p>18 That's the law firm.</p> <p>19 A Okay.</p> <p>20 Q Do you see that?</p> <p>21 A Yes.</p> <p>22 Q So why don't you follow Mr. Locke's</p> <p>23 advice and take a look at it, and I'll ask you</p> <p>24 some questions.</p> <p>25 A (Peruses document.)</p>

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<p>1 MR. TISI: Actually, would this be a 2 good time for a break? 3 MS. FRAZIER: Yes. 4 MR. TISI: For you, I will do almost 5 anything. 6 THE VIDEOGRAPHER: All right. Off the 7 record, Counsel? 8 MS. FRAZIER: Thank you. 9 THE VIDEOGRAPHER: The time is 10:43 10 a.m. We're going off the record. 11 (Recess.) 12 THE VIDEOGRAPHER: The time is 10:58 13 a.m., and we are back on the record. 14 BY MR. TISI: 15 Q Dr. Loretz, have you had an opportunity 16 to look at Exhibit No. 50, the e-mail from 17 Mr. Glenn at Crowell & Moring? 18 A Yes. 19 Q And Mr. Glenn worked for Crowell & 20 Moring, but you know that he's a toxicologist, 21 correct? 22 A I probably knew that at the time. 23 Q Okay. And do you know that he was 24 also -- previous to working for the law firm 25 representing Imerys, do you know that he was also</p>	<p>1 cancer." 2 Do you see that? 3 A Yes. 4 Q Okay. So it's talking about two 5 different papers, right? 6 A Yes. 7 Q Okay. So does this refresh your 8 recollection as to whether or not you were aware 9 in the 2000s that Huncharek and Muscat were 10 actually consultants for the law firm representing 11 Imerys, which is -- is Luzenac. 12 A I would say this would refresh my 13 memory, yes. 14 Q Okay. So we have on our chart here in 15 2005 -- 2006 is IARC review, 2005 -- and I'm going 16 to try to write real -- because on a break folks 17 told me my handwriting was abysmal. So we have 18 "Huncharek, Muscat, two papers." One a review 19 and, two, diaphragm. 20 Is that correct? That's what that 21 document says? 22 A What year are you putting that -- 23 Q 2005. 24 A Or it looks those -- yeah, I don't know 25 when -- the publication date, though.</p>
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<p>1 a prior president of the Industrial Minerals 2 Association of North America? 3 A I don't -- that doesn't sound familiar. 4 Q Okay. So it talks to Mark Ellis at IMA 5 North America and to yourself. 6 And I'm interested in the first 7 paragraph. The first paragraph says: "As you may 8 know, we represent Luzenac America in assisting 9 them in preparation of comments to the NTP and 10 IARC regarding carcinogen classification of talc. 11 They have sponsored projects with Drs. Huncharek 12 and Muscat related to reviewing the literature on 13 talc and ovarian cancer, and conducting a 14 meta-analysis of talc and ovarian cancer." 15 Do you see that? 16 A Yes. 17 Q Okay. So two different things, 18 reviewing the literature on talc and conducting a 19 meta-analysis. 20 Do you see that? 21 A Yes. 22 Q Okay. It says: "Both are nearing 23 completion, and in short, the results of the 24 meta-analysis do not find a relationship for usage 25 of talc on contraceptive diaphragms and ovarian</p>	<p>1 Q Right. The publications, actually you 2 know that they -- they actually published two 3 articles bearing on the very same topic 4 subsequently. 5 A Yes, exactly. 6 Q Okay. And I'm going to identify them 7 again to put on our timeline. 8 A Okay. 9 (Exhibit No. 51 was marked for 10 identification.) 11 BY MR. TISI: 12 Q I'm going to attach Exhibit No. 51, 13 which is a meta-analysis on diaphragms. 14 Is that -- and that's dated 2006. I'm 15 sorry, it's dated 2007. Correct? 16 A Correct. 17 Q And I'm going to start using below the 18 line, so it's 2007. And diaphragm publication, 19 I'll write "Huncharek and Muscat." 20 And what exhibit is that? I wrote 21 that -- 22 A 51. 23 (Exhibit No. 52 was marked for 24 identification.) 25 BY MR. TISI:</p>

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<p>1 Q Okay. And then we have Exhibit No. 52</p> <p>2 is a critical review article that they wrote.</p> <p>3 And you're familiar with that article,</p> <p>4 right?</p> <p>5 A Yes.</p> <p>6 Q And when I say you reviewed, you -- you</p> <p>7 were familiar with it, you were familiar with it</p> <p>8 at the time, right?</p> <p>9 A At the time of its --</p> <p>10 Q Publication.</p> <p>11 A I assume --</p> <p>12 Q Or shortly thereafter.</p> <p>13 A Yeah, I assume so, yes.</p> <p>14 Q So 2008, this is the critical review,</p> <p>15 talc and ovarian cancer. And this is 2008. And</p> <p>16 this is Exhibit 52. And that's Huncharek and</p> <p>17 Muscat.</p> <p>18 Okay. And so far we have Dr. Muscat</p> <p>19 appearing in 2000. Correct?</p> <p>20 A Yes.</p> <p>21 Q We have him working on papers in 2005</p> <p>22 for the lawyers representing Imerys, correct?</p> <p>23 A Yes.</p> <p>24 Q Which you were aware of.</p> <p>25 2007, they write a publication. And</p>	<p>1 THE WITNESS: And I guess I would again</p> <p>2 say that independent in the sense that these are</p> <p>3 their conclusions, but -- and submitted on behalf</p> <p>4 of us, which was clear.</p> <p>5 BY MR. TISI:</p> <p>6 Q Right.</p> <p>7 A On behalf of industry.</p> <p>8 Q But they had been long-time consultants</p> <p>9 for the industry. Correct?</p> <p>10 A They had been consulting before then,</p> <p>11 yes.</p> <p>12 Q Okay. For at least 15 -- on talc for at</p> <p>13 least 15, 18 years, correct?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Where did you come up with</p> <p>16 that? 2000 --</p> <p>17 BY MR. TISI:</p> <p>18 Q 2000 to 2008 -- I'm sorry. 2000 --</p> <p>19 A 2009.</p> <p>20 Q Okay. Let's say nine years, you're</p> <p>21 right. You're right.</p> <p>22 All right. So now let's move forward.</p> <p>23 We talked about IARC.</p> <p>24 So -- now, I want to again fill out the</p> <p>25 timeline so the jury understands what's going on.</p>
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<p>1 then in 2008, they write a publication. And</p> <p>2 2009 -- '8 and '9, they're filing the petition --</p> <p>3 they're drafting the response to the petition as</p> <p>4 a, quote, independent review. Right?</p> <p>5 A Yes.</p> <p>6 Q But the truth of the matter is, as we</p> <p>7 showed on our timeline, is they had been a</p> <p>8 consistent consultant not only for PCPC but for</p> <p>9 other members of the PCPC throughout the 2000s,</p> <p>10 correct?</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: I mean, they're -- they're</p> <p>13 filing -- the filing that we did came through us.</p> <p>14 That was very clear.</p> <p>15 BY MR. TISI:</p> <p>16 Q Okay. That's a different question.</p> <p>17 Okay. You identified this as an independent</p> <p>18 review, right?</p> <p>19 A That -- yes.</p> <p>20 Q Okay. But when I asked you before are</p> <p>21 you sure they're independent, these -- these two</p> <p>22 scientists had been paid consultants for not only</p> <p>23 PCPC but the industry for at least 15 years before</p> <p>24 this was filed, correct?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 2008, Dr. Epstein for the Cancer</p> <p>2 Prevention Coalition files -- asks that warnings</p> <p>3 be mandated, correct?</p> <p>4 A Correct.</p> <p>5 Q Your organization files an opposition to</p> <p>6 that in July of 2009, correct?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Right. We filed saying we</p> <p>9 didn't think those warnings should be mandated.</p> <p>10 BY MR. TISI:</p> <p>11 Q With the FDA.</p> <p>12 A Correct.</p> <p>13 Q Filed -- signed by Dr. Bailey, who used</p> <p>14 to work at the FDA in the very division that would</p> <p>15 be considering the petition, correct?</p> <p>16 A That's correct.</p> <p>17 Q Okay. And do you know whether or not</p> <p>18 any other organizations were even aware of this</p> <p>19 petition to weigh in on it? In other words, are</p> <p>20 you aware of anybody else who filed a response to</p> <p>21 the FDA -- I mean to the Citizen's Petition?</p> <p>22 A I may have known at the time, but I</p> <p>23 don't recall now.</p> <p>24 (Exhibit No. 53 was marked for</p> <p>25 identification.)</p>

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<p>1 BY MR. TISI:</p> <p>2 Q All right. I went to the FDA website</p> <p>3 and pulled a copy -- Exhibit 53, I pulled a copy</p> <p>4 of it, and as I read it, the only comment that was</p> <p>5 actually provided was by the PCPC.</p> <p>6 Does that refresh your recollection?</p> <p>7 A As I say, I can't remember, but I have</p> <p>8 no reason not to think that's true.</p> <p>9 Q Okay. And just to kind of fill out a</p> <p>10 timeline because I want to make it clear that I</p> <p>11 don't want to hide anything from the jury here, in</p> <p>12 2015, the petition was denied.</p> <p>13 A That's correct.</p> <p>14 Q So write "2005, FDA," and --</p> <p>15 MR. TISI: Do you have a copy of the</p> <p>16 denial? I'll attach that in a moment.</p> <p>17 BY MR. TISI:</p> <p>18 Q And so from the outside, what the FDA</p> <p>19 had before it was the Epstein petition and the</p> <p>20 PCPC response. Is that -- and then some four</p> <p>21 years later or five years later, it denied the</p> <p>22 petition.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Okay.</p> <p>25 BY MR. TISI:</p>	<p>1 A That's true.</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 BY MR. TISI:</p> <p>5 Q That's true, correct?</p> <p>6 A Yes.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 BY MR. TISI:</p> <p>9 Q And just for clarity of the record, the</p> <p>10 denial letter from the FDA dated April 2014 -- I'm</p> <p>11 sorry, it's dated 2014.</p> <p>12 A Yeah, it's '14. I wasn't sure about</p> <p>13 that.</p> <p>14 Q I stated 2015. You know, you're</p> <p>15 correct. You're correct. It's Exhibit No. 54.</p> <p>16 (Exhibit No. 54 was marked for</p> <p>17 identification.)</p> <p>18 BY MR. TISI:</p> <p>19 Q Now, I want to talk about -- now that we</p> <p>20 have our timeline out of the way, I want to talk</p> <p>21 about the Citizen's Petition and the arguments you</p> <p>22 made in them and the circumstances surrounding its</p> <p>23 actual filing. Okay?</p> <p>24 A Yes.</p> <p>25 Q Now, prior to the actual filing of</p>
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<p>1 Q Is that -- is that correct?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: As far as I know, yes. As</p> <p>4 I say --</p> <p>5 BY MR. TISI:</p> <p>6 Q All right. Is there anything -- do you</p> <p>7 know why it took the FDA five years or six years</p> <p>8 to actually act on this petition?</p> <p>9 A I don't. I know that it typically takes</p> <p>10 them years to respond to petitions, but I couldn't</p> <p>11 say anything specific about this one.</p> <p>12 Q Well, petitions related to cosmetics, on</p> <p>13 the scheme of things -- I mean you work with the</p> <p>14 FDA, you know the FDA does a lot of different</p> <p>15 things. It deals with pharmaceutical drugs, it</p> <p>16 deals with over-the-counter drugs, it deals with</p> <p>17 the blood supply, it deals with a lot of different</p> <p>18 things, correct?</p> <p>19 A Not the Office of Cosmetics and Colors,</p> <p>20 but other parts of the FDA, sure.</p> <p>21 Q Right. But the -- but the FDA as a --</p> <p>22 as a whole -- I mean would it be fair to say that</p> <p>23 on a scale of things, cosmetics are not as heavily</p> <p>24 regulated or looked at as is, for example,</p> <p>25 pharmaceutical drugs or over-the-counter drugs?</p>	<p>1 the -- the opposition to this Citizen's Petition,</p> <p>2 we'll just -- can I just call it "the opposition,"</p> <p>3 and we know we're talking about something</p> <p>4 containing the opposition to the Citizen's</p> <p>5 Petition?</p> <p>6 A Yes.</p> <p>7 Q Prior to filing the PCPC's opposition in</p> <p>8 July, and we looked at this earlier, you and --</p> <p>9 when I say "you," I mean you personally -- you and</p> <p>10 your colleagues at the PCPC and the companies</p> <p>11 represented by the lawyers on this table went and</p> <p>12 met with the FDA about the Citizen's Petition,</p> <p>13 correct?</p> <p>14 MR. LOCKE: When?</p> <p>15 THE WITNESS: One other company as well.</p> <p>16 BY MR. TISI:</p> <p>17 Q Unilever.</p> <p>18 A Unilever.</p> <p>19 Q Okay. But certainly Johnson & Johnson</p> <p>20 is by far the biggest contributor to -- in terms</p> <p>21 of resources to the Talc Task Force, correct, in</p> <p>22 terms of money?</p> <p>23 MS. FRAZIER: Objection.</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: I think what I've seen,</p>

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<p>1 they're the biggest contributor.</p> <p>2 BY MR. TISI:</p> <p>3 Q I mean by a factor of a lot, correct?</p> <p>4 MS. FRAZIER: Object to form.</p> <p>5 BY MR. TISI:</p> <p>6 Q I mean, it's a big -- they're the --</p> <p>7 they're the major funder of the Talc Task Force,</p> <p>8 correct?</p> <p>9 MS. FRAZIER: Object to form.</p> <p>10 THE WITNESS: But they're not the only</p> <p>11 funder.</p> <p>12 BY MR. TISI:</p> <p>13 Q And in the top two or three is Imerys as</p> <p>14 well, correct?</p> <p>15 A That's correct.</p> <p>16 Q Okay. So -- while there may be many</p> <p>17 other members of the -- that have an interest in</p> <p>18 talc, the two big gorillas in the room are J&J,</p> <p>19 the manufacturer of talcum powder products like</p> <p>20 Johnson & Johnson's baby powder and Shower to</p> <p>21 Shower, and the mining company who provides that</p> <p>22 talc for use in the product, correct?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 MS. FRAZIER: Objection to form.</p> <p>25 THE WITNESS: I mean we have --</p>	<p>1 THE WITNESS: That sounds roughly right</p> <p>2 from the numbers I've seen.</p> <p>3 BY MR. TISI:</p> <p>4 Q Okay. And so the PCPC and Johnson &</p> <p>5 Johnson and Imerys and Unilever went to go meet</p> <p>6 with the FDA about the Citizen's Petition,</p> <p>7 correct?</p> <p>8 A Yeah, I'm not sure if it was set up</p> <p>9 specifically about the Citizen's Petition, but I</p> <p>10 know that certainly got discussed. So yes.</p> <p>11 Q Well, we'll talk -- we're going to talk</p> <p>12 about -- have you reviewed those -- those memos</p> <p>13 before today?</p> <p>14 A I think I -- I reviewed the memo. I'm</p> <p>15 not sure what all the discussion went into setting</p> <p>16 up that meeting, but --</p> <p>17 Q Okay. Well, did you --</p> <p>18 A -- I don't disagree with that.</p> <p>19 Q But did you try to investigate that?</p> <p>20 Because that's an important point. How did that</p> <p>21 meeting get set up?</p> <p>22 A I know Dr. Bailey set it up.</p> <p>23 Q Dr. Bailey, the guy who used to work at</p> <p>24 the division --</p> <p>25 A Correct.</p>
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<p>1 THE REPORTER: Counsel, we can't hear</p> <p>2 you down here.</p> <p>3 MS. FRAZIER: No, it's okay. I was</p> <p>4 just objecting to being called a gorilla.</p> <p>5 MR. TISI: I'll call you a gorilla, but</p> <p>6 let's rephrase the question. Okay?</p> <p>7 BY MR. TISI:</p> <p>8 Q If you were to rank all of the -- I mean</p> <p>9 I've seen lists somewhere between 20 and 30 people</p> <p>10 who make or have an interest in talcum powder</p> <p>11 products. Correct?</p> <p>12 A Yes.</p> <p>13 Q Okay. The major ones if you were to</p> <p>14 rank them are going to be Johnson & Johnson,</p> <p>15 correct?</p> <p>16 A It certainly is one of the companies</p> <p>17 that has a major interest. There are other</p> <p>18 companies and they get their say on calls and</p> <p>19 meetings, et cetera.</p> <p>20 Q All right. Would it surprise you that</p> <p>21 between the two of them, they provide -- Imerys</p> <p>22 and Johnson & Johnson provide between 65 and 70</p> <p>23 percent of the funding for the talc-related</p> <p>24 activities of the PCPC?</p> <p>25 MR. DONATH: Objection to form.</p>	<p>1 Q -- called the division he used to work</p> <p>2 for to see if he could set up a meeting?</p> <p>3 A Yes.</p> <p>4 Q And that meeting occurred in May of</p> <p>5 2009, correct?</p> <p>6 A I don't recall, but that sounds about</p> <p>7 right.</p> <p>8 Q Okay. So the office -- there was a</p> <p>9 meeting at the Office of Cosmetics and Colors set</p> <p>10 up by Dr. Bailey who used to run that division,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q And you were at that meeting?</p> <p>14 A Yes.</p> <p>15 Q And Dr. Bailey's former subordinate</p> <p>16 Dr. Katz was at that meeting?</p> <p>17 A You've said she used to work for him.</p> <p>18 I -- I have no reason not to believe you, but,</p> <p>19 yes, she was there.</p> <p>20 Q Okay. And I'm going to attach</p> <p>21 Dr. Bailey's report of that meeting, and I think</p> <p>22 there's an error in it, but I'm going to correct</p> <p>23 it and see if we can work through it together.</p> <p>24 This is Exhibit No. 55.</p> <p>25 (Exhibit No. 55 was marked for</p>

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<p>1 identification.)</p> <p>2 BY MR. TISI:</p> <p>3 Q And just I can correct the error so we</p> <p>4 can correct it going forward. It's from John</p> <p>5 Bailey from Personal Care Council dated Monday,</p> <p>6 May 11th, 2009.</p> <p>7 Do you see that?</p> <p>8 A I'm sorry. The -- oh, yes.</p> <p>9 Q The e-mail.</p> <p>10 A Right, the e-mail.</p> <p>11 Q It's to, among other things, you?</p> <p>12 A Yes.</p> <p>13 Q Okay. And it's a -- meeting notes from</p> <p>14 the meeting of the FDA on talc.</p> <p>15 A Yes.</p> <p>16 Q Okay. And it says: "All: Below are my</p> <p>17 attached notes from the FDA meeting on Friday."</p> <p>18 Correct?</p> <p>19 A Yes.</p> <p>20 Q Okay. And these were recounting a</p> <p>21 note -- notes that happened that prior Friday,</p> <p>22 correct?</p> <p>23 A Yes.</p> <p>24 Q And so the meeting with the FDA says</p> <p>25 May 8th, 2008. Do you see that?</p>	<p>1 predominant number of people at this -- at this</p> <p>2 meeting were from the office that Dr. Bailey ran,</p> <p>3 the Office of Cosmetics and Colors, I was correct?</p> <p>4 A I would say you were correct, yes.</p> <p>5 Q Thank you. I like being correct.</p> <p>6 And you attended that meeting?</p> <p>7 A I did.</p> <p>8 Q Okay. Have you seen the final -- now,</p> <p>9 this is a fairly lengthy, several single-spaced</p> <p>10 pages of notes about what happened at that</p> <p>11 meeting?</p> <p>12 A Okay. Yes.</p> <p>13 Q Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Okay. Have you seen the FDA version</p> <p>16 of -- of that?</p> <p>17 A I think I have in my preparation for</p> <p>18 this.</p> <p>19 Q Well, it says: The action items from</p> <p>20 the meeting. "The FDA has to prepare notes of the</p> <p>21 meeting." It's at the very end, the last</p> <p>22 paragraph.</p> <p>23 A Mm-hmm.</p> <p>24 Q The FDA notes I'm going to show you are</p> <p>25 Exhibit 56.</p>
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<p>1 A Yes.</p> <p>2 Q Okay. Do you agree with me that it's</p> <p>3 likely to be May 8th, 2009?</p> <p>4 A I do agree with you.</p> <p>5 Q Okay. Okay. And in other iterations of</p> <p>6 this I see 2009, but just for the record and for</p> <p>7 our timeline going back to it, the meeting</p> <p>8 happened -- so I'm going to put "FDA meeting."</p> <p>9 And I'm going to do that in red.</p> <p>10 In 2000 -- in May of 2009, right?</p> <p>11 A Yes.</p> <p>12 Q "May '09."</p> <p>13 And when I mentioned attendance for the</p> <p>14 FDA, the Acting Commissioner was there. Do you</p> <p>15 see that?</p> <p>16 A Yes.</p> <p>17 Q Okay. And the director for the Food</p> <p>18 Safety and Applied Nutrition was there. Correct?</p> <p>19 A Yes.</p> <p>20 Q But all the other people there,</p> <p>21 including people that he didn't recognize, were</p> <p>22 from the Office of Cosmetics and Colors?</p> <p>23 A That's what it says, yes.</p> <p>24 Q All right. So when I asked you before</p> <p>25 whether or not this was the primary -- the</p>	<p>1 (Exhibit No. 56 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. TISI:</p> <p>4 Q And the FDA meeting notes is like a</p> <p>5 paragraph and two action items, correct?</p> <p>6 A Yes.</p> <p>7 Q Okay. So the notes that we have of this</p> <p>8 meeting are much more fulsome as recorded by</p> <p>9 Dr. Bailey?</p> <p>10 A Yes.</p> <p>11 Q There's a lot more detail in them.</p> <p>12 A So it appears, yes.</p> <p>13 Q Okay. And I asked you before whether or</p> <p>14 not the purpose of this meeting was to discuss the</p> <p>15 Citizen's Petition. Do you remember that?</p> <p>16 A Yes.</p> <p>17 Q Okay. And the first bullet point, it</p> <p>18 says: "A petition has been submitted by the FDA</p> <p>19 requesting a warning and hearing."</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q And the first paragraph, full paragraph</p> <p>23 says: "Dr. Katz opened the meeting."</p> <p>24 And Dr. Katz at that point was the</p> <p>25 director of the FDA Division of Cosmetics and</p>

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<p>1 Colors at that point, correct?</p> <p>2 A Yes.</p> <p>3 Q Okay. By saying that: "Counsel had</p> <p>4 requested the meeting, but she wanted to make the</p> <p>5 point that the FDA would not talk about the</p> <p>6 Citizen's Petition on talc as it was still under</p> <p>7 review."</p> <p>8 Do you see that?</p> <p>9 A Actually, I'm sorry, where are you</p> <p>10 exactly? Oh, there we go. Okay.</p> <p>11 Q Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Okay. Do you remember that</p> <p>14 specifically, that she started out saying, you</p> <p>15 know, Great you're all here, but we don't want to</p> <p>16 discuss the Citizen's Petition?</p> <p>17 A I don't remember it, but I -- I accept</p> <p>18 that that is what happened.</p> <p>19 Q Okay. But then Dr. Bailey corrected</p> <p>20 her, and said -- "Dr. Bailey pointed out the</p> <p>21 agenda that was provided was to discuss the</p> <p>22 information related in the petition."</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q Correct?</p>	<p>1 Q It was requested. An agenda was</p> <p>2 provided to the FDA, correct?</p> <p>3 A I think that's what it says. I don't</p> <p>4 recall that, but --</p> <p>5 Q Have you seen the agenda in connection</p> <p>6 with your preparation today?</p> <p>7 A I don't think so.</p> <p>8 Q Okay. I didn't see it either. It might</p> <p>9 be -- it might be around, but I just -- maybe I</p> <p>10 just didn't see it.</p> <p>11 Was anyone -- since the agenda, as</p> <p>12 Dr. Bailey pointed out, was -- involved the</p> <p>13 Citizen's Petition, right?</p> <p>14 A That's what it says, yes.</p> <p>15 Q I'm curious. Did Dr. Bailey propose</p> <p>16 that the guy who wrote the Citizen's Petition be</p> <p>17 invited to the meeting?</p> <p>18 A I don't believe so, no.</p> <p>19 Q Do you know whether or not Dr. Epstein</p> <p>20 or the -- any of the members of the American --</p> <p>21 the Cancer Prevention Coalition were asked to</p> <p>22 attend the meeting by the FDA or suggested by</p> <p>23 PCPC?</p> <p>24 A Not that I'm aware.</p> <p>25 Q I mean you are interested in a fulsome</p>
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<p>1 MR. LOCKE: Objection to form.</p> <p>2 THE WITNESS: Well, that's what it says,</p> <p>3 yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q All right. And in fact, you brought</p> <p>6 with you Dr. Muscat and Dr. Huncharek's</p> <p>7 opposition, the opposition that had not yet been</p> <p>8 filed?</p> <p>9 A It was -- right, it was talked about.</p> <p>10 Q It was talked about, and it was</p> <p>11 summarized for the FDA?</p> <p>12 A Yes, that's what it says.</p> <p>13 Q So the FDA says, We're not going to talk</p> <p>14 about it, but then talked about it.</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: Well, it says that she</p> <p>17 then -- Dr. Katz then clarified to say that you</p> <p>18 can talk about it, but we're not going to discuss</p> <p>19 its status.</p> <p>20 BY MR. TISI:</p> <p>21 Q Okay. So my question to you is, was</p> <p>22 anybody from the --</p> <p>23 Now, this meeting was set up by the --</p> <p>24 by Dr. Bailey at the PCPC, correct?</p> <p>25 A Yes. Or requested, yes.</p>	<p>1 discussion of the science, right?</p> <p>2 A I -- I think for this meeting we were --</p> <p>3 well, I guess the notes speak for themselves.</p> <p>4 Q Well -- okay. My question was, you've</p> <p>5 talked to me before -- you said before when I was</p> <p>6 asking you questions about this petition, you</p> <p>7 said, Well, we didn't think the science supported</p> <p>8 it. Correct?</p> <p>9 A Support the need for a warning, yes.</p> <p>10 Q Right. But we all agreed that there was</p> <p>11 a -- a debate in the medical and scientific</p> <p>12 community about what the science meant, correct?</p> <p>13 A Yes.</p> <p>14 Q And that had been going on for decades,</p> <p>15 correct?</p> <p>16 A Yes.</p> <p>17 Q Okay. And you had a definite point of</p> <p>18 view on the issue, correct?</p> <p>19 A Yes.</p> <p>20 Q On behalf of your members, right?</p> <p>21 A Yes.</p> <p>22 Q And somebody who had a different point</p> <p>23 of view presented a petition to the FDA. Correct?</p> <p>24 A Yes.</p> <p>25 Q And you asked for a meeting at the FDA</p>

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<p>1 to discuss, among other things, that petition, 2 correct? 3 A Yes. 4 Q And you actually submitted an agenda. 5 True? 6 A That's what it says. 7 Q And the agenda was clear that you wanted 8 to discuss the petition, correct? 9 A I would assume so based on what this 10 says on the subject matter. 11 Q And you walked in prepared to discuss 12 the petition. You even brought with you 13 Dr. Muscat and Dr. Huncharek's commissioned work 14 on behalf of the industry, correct? 15 A That seems to be what it says, yes. 16 Q And -- well, it's not only what it says, 17 it happened, correct? 18 A Yes. 19 Q And when you're testifying about PCPC -- 20 A Yes. 21 Q -- this is one of the topics you were 22 prepared to talk about. 23 A Okay. 24 Q Right? 25 A Yes.</p>	<p>1 if you were really interested in the scientific 2 question, why not invite the -- why not say, Maybe 3 we should have Dr. Epstein come? 4 A I think we knew where Dr. Epstein stood, 5 and we disagreed with him. 6 Q Right. So why not have him come to 7 present his position? 8 A I don't think this was the meeting for 9 that. 10 Q Okay. And -- the FDA initially 11 expressed its reservation about the meeting, 12 correct? 13 MR. LOCKE: Objection. 14 BY MR. TISI: 15 Q It said -- it said -- initially said 16 that they didn't want to talk about the pending 17 Citizen's Petition, correct? 18 MR. LOCKE: Objection. 19 THE WITNESS: And then said that you can 20 talk to us, but we're not going to talk about -- 21 BY MR. TISI: 22 Q Because you were already there. 23 A Well, they accepted the meeting, though. 24 So if there really was an agenda that -- I'm 25 sure it would have shown that, and they could have</p>
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<p>1 Q So you walk in there, and did you say to 2 them, You know, we really want -- this is an 3 important issue, because we agreed that it's an 4 important issue. Ovarian cancer and talc was an 5 important issue, right? 6 A Yes. 7 Q Did you say to them, You know, why don't 8 we get Dr. Epstein to come to this meeting so we 9 can have a fulsome discussion of the pros and cons 10 of what the science means? 11 A I -- I think this was not a meeting 12 where that was -- this was not that meeting. I 13 mean we knew where Dr. Epstein stood. 14 Q Well, they knew where you stood too, 15 but you -- 16 A Right. 17 Q -- you accepted a meeting anyway or you 18 asked for a meeting anyway to discuss the issues, 19 right? 20 A Yes. 21 MR. LOCKE: Objection. Form. 22 THE WITNESS: And they could have said 23 no, but they were willing to meet with us. 24 BY MR. TISI: 25 Q The were willing to meet with you, but</p>	<p>1 said -- I mean they would have asked what -- what 2 did we want to talk about. 3 Q Right. But the first sentence here 4 indicates a little bit of interpreting it fairly, 5 a little bit initial hesitation -- 6 A Sure. 7 Q -- by the FDA to discussing a petition 8 with only one party there and without the other. 9 True? 10 A Well -- 11 MR. LOCKE: Objection. 12 BY MR. TISI: 13 Q True? 14 MR. LOCKE: Objection. 15 THE WITNESS: It's under advisement. I 16 don't know if it's because -- 17 BY MR. TISI: 18 Q I got -- we got to get the objection in, 19 and then you got to answer. 20 A Sorry. 21 Q I'm sorry. Go ahead. I'm sorry. 22 A Just I don't know that -- I think 23 probably their normal policy is they're not going 24 to talk about things that are under advisement. 25 So I don't know that it's because the other party</p>

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<p>1 wasn't there or it's just -- we're working this</p> <p>2 through, so we're not going to -- we're not going</p> <p>3 to give you -- tell you where we stand right now.</p> <p>4 You can talk to us.</p> <p>5 And then later on she asked that we</p> <p>6 submit, formally submit our information, which we</p> <p>7 did.</p> <p>8 Q All right. And asked you some follow-up</p> <p>9 questions, true?</p> <p>10 A Yes.</p> <p>11 Q Okay. Which you did?</p> <p>12 A Yes.</p> <p>13 Q Do you know whether or not the FDA ever</p> <p>14 reached out to Dr. -- Dr. Epstein or anybody else</p> <p>15 to say, Look, you know, we would like to get your</p> <p>16 further input. We met with -- with the industry</p> <p>17 and their trade organization. They raised some</p> <p>18 issues about dose response, about contamination</p> <p>19 with talc, about bio -- with asbestos, about</p> <p>20 biologic plausibility, about all the issues that</p> <p>21 were in the Citizen's Petition. What is your</p> <p>22 response to that?</p> <p>23 Do you know if that was ever done by the</p> <p>24 FDA?</p> <p>25 A I think some of reaching out to us, and</p>	<p>1 A Yes.</p> <p>2 Q Okay. But you wanted to actually get in</p> <p>3 the room and actually speak with them, right?</p> <p>4 A Yes.</p> <p>5 Q Okay. You know, because -- because this</p> <p>6 was important to your members, right?</p> <p>7 A Yes.</p> <p>8 Q Okay. The American Cancer Coalition was</p> <p>9 representing consumers, right?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q Patients?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I'm not sure who they</p> <p>15 represent, but -- yes.</p> <p>16 BY MR. TISI:</p> <p>17 Q Was there anybody in that room on May 8,</p> <p>18 2009, that represented patients, doctors,</p> <p>19 consumers?</p> <p>20 MR. LOCKE: Other than the FDA?</p> <p>21 THE WITNESS: I was going to say the</p> <p>22 Commissioner of the FDA, I would --</p> <p>23 BY MR. TISI:</p> <p>24 Q I'm asking you other than the -- the FDA</p> <p>25 was trying to decide a question. Correct?</p>
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<p>1 the follow-up questions were ones that were</p> <p>2 specific to industry, how do you source talc, that</p> <p>3 kind of thing. So -- so certainly that -- we have</p> <p>4 to be the audience for that.</p> <p>5 Q Right. My question is, do you know</p> <p>6 whether or not in the four or five years between</p> <p>7 the time that you all were meeting with the FDA</p> <p>8 and the time they ultimately came down with a</p> <p>9 conclusion, that anybody from the FDA ever reached</p> <p>10 out to anybody on the other side of the debate and</p> <p>11 said, Now we've heard from industry, we met with</p> <p>12 J&J, we met with Imerys, we had Unilever there, we</p> <p>13 had PCPC there. We have some questions as to what</p> <p>14 this data means too. What is your response to</p> <p>15 that?</p> <p>16 Do you know whether that ever happened?</p> <p>17 A No. But I would say their petition kind</p> <p>18 of speaks, and then we have a response, and then</p> <p>19 again some -- a lot of the industry questions were</p> <p>20 regarding sourcing, the kind of things that were</p> <p>21 real industry-only questions.</p> <p>22 Q But your petition spoke too, right? You</p> <p>23 had a -- you put a 30-page response --</p> <p>24 A Oh yes.</p> <p>25 Q -- by Huncharek and Muscat.</p>	<p>1 A Yes.</p> <p>2 Q A scientific question. Right?</p> <p>3 A Yes.</p> <p>4 Q In fact, Dr. -- in here Dr. -- the</p> <p>5 Acting Commissioner said --</p> <p>6 A Sharfstein.</p> <p>7 Q -- said he had only heard it because of</p> <p>8 some Korean issue, Korean talc sourcing, correct?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I think that's in the</p> <p>11 minutes.</p> <p>12 BY MR. TISI:</p> <p>13 Q Right. It was clear to you that -- that</p> <p>14 they had not been really focused -- at least the</p> <p>15 Commission had not really been focused on the</p> <p>16 issue, correct?</p> <p>17 MR. LOCKE: You mean the Commissioner?</p> <p>18 MR. TISI: I'm asking the Commissioner.</p> <p>19 BY MR. TISI:</p> <p>20 Q You were providing a lot of information</p> <p>21 that they did not have.</p> <p>22 A Again, a lot --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: -- of our information -- I</p> <p>25 think their questions regarded, again industry,</p>

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<p>1 again sourcing, how do you --</p> <p>2 BY MR. TISI:</p> <p>3 Q That came up too.</p> <p>4 A Right, and that's -- you know, that's</p> <p>5 not a question --</p> <p>6 Q But you came in with the epidemiology --</p> <p>7 the first paragraphs here deal with the</p> <p>8 epidemiology.</p> <p>9 For example, it says: "The Council</p> <p>10 submission and the -- and the Citizen's Petition</p> <p>11 were briefly summarized. The response was</p> <p>12 prepared by two epidemiologists, Dr. Michael</p> <p>13 Huncharek and Dr. Muscat, with a cover letter from</p> <p>14 the Council. In their document Huskarek --</p> <p>15 Huncharek and Muscat provide a summary of each of</p> <p>16 the 12 publications cited in the petition."</p> <p>17 Do you see all that?</p> <p>18 A Yes.</p> <p>19 Q "It was noted that half the publications</p> <p>20 are either reviews or do not provide new data or</p> <p>21 address aspects of ovarian cancer or talc but do</p> <p>22 not provide a link between the two. The</p> <p>23 submission then provides an overall summary of</p> <p>24 epidemiology relating to talc and ovarian cancer,</p> <p>25 noting that the excess risk is small and often not</p>	<p>1 previously worked, correct?</p> <p>2 A That's true.</p> <p>3 Q In fact, that's why you hired him,</p> <p>4 right? You hired him because of experience with</p> <p>5 this particular department.</p> <p>6 A We hired him because of his -- I mean,</p> <p>7 obviously the fact that he had FDA background</p> <p>8 was -- was considered a good thing.</p> <p>9 Q In this department, correct?</p> <p>10 A Yes.</p> <p>11 Q And you hired him knowing full well that</p> <p>12 talc was a very important issue that was coming --</p> <p>13 what that might be dealt with by this department,</p> <p>14 correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: As far as I know, and I</p> <p>17 had nothing to do with the hiring of Dr. Bailey,</p> <p>18 it wasn't about a specific issue at all. It</p> <p>19 was -- I mean, the general fact was he had a</p> <p>20 wonderful background with FDA and cosmetics, and</p> <p>21 that made him a valuable employee to the Council,</p> <p>22 to CTFA.</p> <p>23 BY MR. TISI:</p> <p>24 Q Now, do you know whether or not prior to</p> <p>25 this meeting --</p>
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<p>1 statistically significant, overall lacks</p> <p>2 dose-response relationship, or in some cases shows</p> <p>3 an inverse dose-response relationship, lacks a</p> <p>4 biological plausible mechanism, and that the</p> <p>5 exposure data is limited."</p> <p>6 There was a discussion of all that</p> <p>7 stuff, right?</p> <p>8 A I'm not sure there was a discussion. I</p> <p>9 think, as I say, she -- it looks like Dr. Katz</p> <p>10 said, You can tell us -- you can talk to us, but</p> <p>11 we're really not going to engage in a discussion.</p> <p>12 We gave this overall summary, and her</p> <p>13 response was, Well, submit it, and then we can</p> <p>14 consider it fully.</p> <p>15 Q Right. But you were in the room and</p> <p>16 Drs. Epstein and no other doctor who thought on</p> <p>17 the other side of this debate was in the room.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q Correct?</p> <p>21 A That's correct.</p> <p>22 Q Okay. And also in the room was your</p> <p>23 senior scientific person who knew all of the</p> <p>24 people who he -- or most of the people at the</p> <p>25 Office of Colors and Cosmetics with whom he</p>	<p>1 A This meeting.</p> <p>2 Q This meeting, May 9th -- May 8th --</p> <p>3 A 2009.</p> <p>4 Q -- 2009.</p> <p>5 This was a formal meeting that was set</p> <p>6 up by Dr. Bailey. Correct?</p> <p>7 A I think you would call it that.</p> <p>8 Q Do you know whether this meeting was</p> <p>9 posted to the website so that other people could</p> <p>10 know it was happening, like the American -- the</p> <p>11 Cancer Prevention Coalition?</p> <p>12 A I don't know.</p> <p>13 Q So they -- they wouldn't even know it</p> <p>14 was happening so they could say, Hey, we'd like to</p> <p>15 be in -- we'd like to be in the room?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 BY MR. TISI:</p> <p>18 Q Right?</p> <p>19 A Again, I don't know if it was posted. I</p> <p>20 really don't know.</p> <p>21 Q Do you know whether there were any</p> <p>22 communications with the FDA about this issue</p> <p>23 before this May meeting?</p> <p>24 A I'm not aware.</p> <p>25 Q Have you seen any documents that refer</p>

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<p>1 to a call that was made, conversations that had 2 been had? 3 A From -- related to the petition? 4 Q Mm-hmm. 5 A Sometime between when it was filed 6 and -- 7 Q Mm-hmm. 8 A You can refresh my memory, but 9 nothing -- I'm not thinking of anything, no. 10 (Exhibit No. 57 was marked for 11 identification.) 12 BY MR. TISI: 13 Q Let me show you Exhibit No. 57. 14 This is not a PCPC document. I'm seeing 15 whether this refreshes your recollection. 16 Now, at the very bottom, and I -- I'm 17 going to ask you to read it, but I'm just going to 18 kind of set the table for you. 19 A Very bottom of the second page? 20 Q So first page. 21 A Okay. 22 Q There's an e-mail from Craig Bernard to 23 Mark Zamek at J&J -- I mean at Rio Tinto. And Rio 24 Tinto is -- is Imerys as well, correct? 25 A I believe so, yes.</p>	<p>1 requesting to have a warning label placed on 2 products containing" -- there is no word, but I 3 think it's -- 4 A Right. 5 Q -- involving talc. 6 A Right. 7 Q "Here is an update on that activity. 8 Kathy Wille of J&J informed me that at a recent 9 science meeting in Washington, D.C., she had a 10 side conversation with a key figure from the FDA 11 cosmetic group responsible for responding to the 12 Citizen's Petition. He indicated that the FDA 13 would rule against the petition and would 14 require -- would not require warning labels on 15 cosmetic products, but the FDA is looking for 16 scientific support from industry that would help 17 justify their position. She suggested that there 18 be a collective group working to have comments 19 submitted to the FDA. Principal among these 20 efforts will be comments that Dr. Muscat and 21 Huncharek are co-developing. 22 "In order to orchestrate the completion 23 of these comments, I have been asked by J&J to 24 meet with them, along with Muscat and Huncharek, 25 at their headquarters in New Jersey on Wednesday,</p>
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<p>1 Q And it's referring to a meeting with 2 J&J. Do you see that? 3 A Yes. 4 Q Okay. If you would read it to yourself, 5 please, and then we can -- 6 A Mm-hmm. 7 Q -- we can go off the record if you want. 8 It doesn't matter to me, but you can read it to 9 yourself. 10 MR. TISI: We can go off the record. 11 MR. LOCKE: No. Let's stay on the 12 record. 13 MR. TISI: Okay. 14 THE WITNESS: (Peruses document.) 15 BY MR. TISI: 16 Q I'm really going to ask you about that 17 first big paragraph. 18 A Okay. 19 Q Okay. First of all, the subject matter 20 is "Meeting with J&J," correct? 21 A Yes. 22 Q Okay. And the first sentence says: 23 "You'll recall a couple of months ago we met with 24 a guy Bob Katsioularis' office, and spoke about 25 the Citizen's Petition with the FDA that is</p>	<p>1 November 19th, in order to review the comments 2 before being provided to Personal Care Products 3 Council." 4 Do you see that? 5 A Yes. 6 Q Okay. I read that correctly, right? 7 A I believe so, yes. 8 Q All right. This would suggest that 9 there was another informal contact with the office 10 of colors, fragrance and -- I'm sorry. I'm 11 blanking. Office of -- 12 A Cosmetic and Colors. 13 Q -- Cosmetics and Colors. 14 Are you aware of it? Does this refresh 15 your recollection? 16 MR. LOCKE: Objection. 17 BY MR. TISI: 18 Q Does this refresh your recollection? 19 A No. 20 Q If there was a side conversation about a 21 Citizen's Petition, in your experience being a 22 liaison with the FDA, would that be inappropriate? 23 MR. LOCKE: Objection. 24 MS. FRAZIER: Object to form. 25 MR. LOCKE: Beyond the scope.</p>

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<p>1 THE WITNESS: I -- I mean I'm not a 2 liaison with the FDA. I -- I don't know if this 3 is referring to the meeting that we had with the 4 FDA or a different meeting. 5 BY MR. TISI: 6 Q Well, the date -- the date of it is 7 November 3rd, 2008, so this would have been a good 8 six months before your meeting -- 9 A Oh, okay. 10 Q -- with the FDA. 11 A Oh, I'm sorry. 12 I -- I mean I just can't comment on 13 this. I don't know if this happened. I don't 14 know if it was -- you know, if it's characterized 15 correctly. 16 Q Well, I'm going to ask you this 17 question. You don't have knowledge of it, I 18 accept you at your word. 19 If this happened, in your experience 20 having side conversations with FDA people about 21 issues that are pending before the FDA, is that 22 appropriate? 23 MR. LOCKE: Objection. 24 MS. FRAZIER: Object to form. 25 MR. LOCKE: And beyond the scope.</p>	<p>1 it was fairly late -- I mean, I think it was 2 reasonably close to when the comments were 3 submitted. 4 BY MR. TISI: 5 Q Do you know? 6 A No. 7 Q Did you investigate that? 8 I mean, one of the categories very 9 specific in our notice of deposition were the 10 circumstances surrounding the Citizen's Petition. 11 Did you -- that's why I asked you in the early -- 12 A Mm-hmm. 13 Q Did you interview or look specifically 14 at the notes pertaining to the Citizen's Petition 15 and perhaps speak to Dr. Bailey about what 16 happened? 17 A Did I speak to him at the time? 18 MR. LOCKE: Objection. It's a compound 19 question. 20 BY MR. TISI: 21 Q Okay. Did you review all the documents 22 at your possession relating to the preparation of 23 the Citizen's Petition? 24 A In preparation for this? 25 Q Yes.</p>
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<p>1 THE WITNESS: I can't imagine an FDA 2 person saying something like -- I mean that would 3 seem to me -- 4 BY MR. TISI: 5 Q Wrong. 6 A -- nothing I've ever seen. 7 Q And it would be wrong, right? 8 MR. LOCKE: Objection. 9 MS. FRAZIER: Object to form. 10 MR. LOCKE: Beyond the scope. 11 THE WITNESS: Again, I don't know if 12 this is properly characterized or under- -- what 13 the understanding was. 14 BY MR. TISI: 15 Q Okay. All right. Now, before we 16 discuss the FDA meeting any further from May of 17 2009, and the industry interpretation of evidence 18 actually filed in the white paper, when -- let's 19 talk about what happened before. 20 The petition was filed in the spring of 21 2008. Do you know when it was that Dr. Bailey was 22 first contacted by J&S to participate in this 23 process? 24 MR. LOCKE: Objection to form. 25 THE WITNESS: I don't. I mean, I think</p>	<p>1 A I'm not sure. 2 Q All right. Did you ask to see the notes 3 from the other defendants that might help you 4 understand better what PCPC's role with respect to 5 the Citizen's Petition was? 6 A No. 7 Q Okay. This is -- 8 MR. LOCKE: Let me just -- I want to 9 clarify, to the extent they were produced. 10 BY MR. TISI: 11 Q Okay. Like, for example, that one that 12 we just showed involved the Citizen's Petition. 13 Had you ever seen that before? 14 A I -- no. 15 Q Okay. Did you speak to -- I mean the 16 two people that were involved in the process, as 17 best as I can tell, from PCPC were you and 18 Dr. Bailey. Right? 19 A That's probably correct, yes. 20 Q Did you speak to Dr. Bailey? 21 A No. 22 Q So you don't know what -- what 23 communications he had, do you? 24 A I -- 25 MR. LOCKE: Objection.</p>

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<p>1 THE WITNESS: I can tell you what I</p> <p>2 think my recollection is, that this was not a</p> <p>3 longstanding thing. This was a -- J&J had -- had</p> <p>4 worked on having a -- Drs. Muscat and Huncharek</p> <p>5 prepare a review, a current review of the</p> <p>6 literature, and thought that that would be</p> <p>7 appropriate to submit. And I suspect that all</p> <p>8 happened fairly soon before we actually submitted</p> <p>9 it.</p> <p>10 BY MR. TISI:</p> <p>11 Q Now, prior to this you had fairly</p> <p>12 consistent -- on this issue, you were -- as best I</p> <p>13 can tell from looking at the overall records that</p> <p>14 were produced in this case, and you can correct me</p> <p>15 if I'm wrong, as I look at the decade or so prior</p> <p>16 to this, you were the primary contact on this</p> <p>17 issue.</p> <p>18 A I would say myself and Dr. McEwen.</p> <p>19 Q Okay. Dr. Bailey really wasn't hands on</p> <p>20 with this issue over the -- as compared to you,</p> <p>21 correct?</p> <p>22 A Well, I guess I think our -- you know,</p> <p>23 our biggest involvement, PCPC's biggest</p> <p>24 involvement, biggest effort related to NTP, and</p> <p>25 Dr. Bailey wasn't there at the time.</p>	<p>1 Q So let me show you an e-mail dated --</p> <p>2 58, this is May 2008, right after the Citizen's</p> <p>3 Petition was filed. It's an internal -- this</p> <p>4 would have been a whole year before the meeting at</p> <p>5 the -- at the FDA.</p> <p>6 And from Kathleen Wille, and it's an</p> <p>7 internal document. I don't expect that you would</p> <p>8 have seen it in realtime. But it's talking about</p> <p>9 the Citizen's Petition and the next steps.</p> <p>10 Do you see it?</p> <p>11 A I'm just reading through now.</p> <p>12 (Peruses document.) Okay.</p> <p>13 Q Okay. And so just as you read this,</p> <p>14 what's happening is the Citizen's Petition is</p> <p>15 filed by Dr. Epstein, and there's kind of a</p> <p>16 mobilization of effort in -- in how to respond to</p> <p>17 that, and it's entitled "Next Steps." Do you see</p> <p>18 that?</p> <p>19 A I'm not sure where --</p> <p>20 Q Second page.</p> <p>21 A Yes.</p> <p>22 Q Okay. And underneath that, one of the</p> <p>23 things they -- two things -- there are three</p> <p>24 things they identify. Secure funding and engage</p> <p>25 experts, and that would be Huncharek and Muscat</p>
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<p>1 Q Okay. And the Citizen's Petition as</p> <p>2 well.</p> <p>3 A Right, but it -- it wasn't -- we weren't</p> <p>4 doing multiple submissions and presenting at</p> <p>5 meetings, and that sort of stuff. So it was --</p> <p>6 Q Right. But in terms of -- and, you</p> <p>7 know, we looked at examples here, but, you know,</p> <p>8 you were kept up to date on the IARC issues, you</p> <p>9 had been communicating with Bob Glenn at -- at --</p> <p>10 I mean I've seen a bunch of them, I could pull</p> <p>11 them out for you.</p> <p>12 But to the extent that the -- the other</p> <p>13 defendants in this case, J&J and Imerys, were</p> <p>14 contacting PCPC about issues related to talc, you</p> <p>15 were prime -- the primary person that would be</p> <p>16 their liaison.</p> <p>17 A Probably. That's probably true.</p> <p>18 Q Okay. Until the Citizen's Petition</p> <p>19 was -- was filed, do you know that they</p> <p>20 contacted -- they wanted to contact Dr. Bailey?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: No, I didn't.</p> <p>23 (Exhibit No. 58 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. TISI:</p>	<p>1 that's named here, and PCPC ultimately paid for</p> <p>2 that, right?</p> <p>3 A Yes.</p> <p>4 Q Okay. Number 2, "Engage internal</p> <p>5 stakeholders." Do you know whether or not any</p> <p>6 public relations people were -- were contacted in</p> <p>7 connection with the Citizen's Petition?</p> <p>8 A I'm not aware --</p> <p>9 MR. LOCKE: Objection. You're referring</p> <p>10 to J&J -- you're asking the witness about J&J?</p> <p>11 MR. TISI: No, I did not.</p> <p>12 BY MR. TISI:</p> <p>13 Q I asked, are you aware of any public</p> <p>14 relations people for anybody that was contacted in</p> <p>15 connection with this Citizen's Petition?</p> <p>16 A I guess I could only answer for PCPC,</p> <p>17 and I'm not aware of any.</p> <p>18 Q Okay. But the third is what I'm most</p> <p>19 interested in, "Determine level of external</p> <p>20 support."</p> <p>21 The first is John Bailey. It says:</p> <p>22 "John Bailey of the Personal Care Products Council</p> <p>23 is out of the office until the next week,</p> <p>24 June 2nd. We will ascertain their plans to</p> <p>25 respond."</p>

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<p>1 Do you see that?</p> <p>2 A Yes.</p> <p>3 Q Okay. It didn't say, We're contacting</p> <p>4 Linda Loretz, are they?</p> <p>5 A That might be because it's Kathy Wille.</p> <p>6 I mean it just kind of depends who within</p> <p>7 Johnson & Johnson is -- is responding.</p> <p>8 Q So do you know whether or not in this</p> <p>9 time frame -- this is a full year before the</p> <p>10 meeting, more than -- with the FDA and more than a</p> <p>11 year before the formal response was filed in July</p> <p>12 of 2009.</p> <p>13 Do you know whether or not at this time</p> <p>14 frame, J&J had been able to contact Dr. Bailey,</p> <p>15 who again had been the prior director of the</p> <p>16 division?</p> <p>17 A Yeah, I don't know what discussions went</p> <p>18 on with --</p> <p>19 Q I don't mean to be factitious about it,</p> <p>20 but wouldn't it make sense to actually -- if you</p> <p>21 are here to testify on that issue, to actually</p> <p>22 speak to Dr. Bailey --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q -- about that issue?</p>	<p>1 Counsel.</p> <p>2 MR. LOCKE: Okay, good.</p> <p>3 BY MR. TISI:</p> <p>4 Q Tell me everything that you know</p> <p>5 happened with respect to the development of the</p> <p>6 response to the Citizen's Petition.</p> <p>7 I know you said it was initiated by J&J.</p> <p>8 Do you know that Imerys had some input -- we saw a</p> <p>9 meeting that -- with Drs. Huncharek and Muscat</p> <p>10 and -- and Imerys in November. Were you at that</p> <p>11 meeting?</p> <p>12 A No.</p> <p>13 Q You know -- did you know it happened?</p> <p>14 A I don't believe so. If I -- I don't</p> <p>15 recall it, no.</p> <p>16 Q Were you given an opportunity to review</p> <p>17 the -- the Citizen's Petition that was actually</p> <p>18 filed on -- on PCPC's behalf?</p> <p>19 A I -- I'm sure I was in the sense that</p> <p>20 obviously if it was something we have had an issue</p> <p>21 with, we wouldn't have submitted it. So I'm going</p> <p>22 to say yes.</p> <p>23 Q And so when you say it was -- it was</p> <p>24 drafted by somebody else, it went out under PCPC's</p> <p>25 name, and to the extent that you're here as a</p>
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<p>1 MR. LOCKE: Objection.</p> <p>2 By the way, it also says, "We will then</p> <p>3 ascertain their plans."</p> <p>4 MR. TISI: I understand.</p> <p>5 THE WITNESS: I mean, I don't think we</p> <p>6 did anything on the petition until later, so I</p> <p>7 kind of read into that that there was not a lot</p> <p>8 going on at this point.</p> <p>9 BY MR. TISI:</p> <p>10 Q Well, there was -- there's a couple of</p> <p>11 things, right, that could go on? Number one is</p> <p>12 actually responding to the petition. Number two</p> <p>13 could actually be speaking to the FDA.</p> <p>14 Do you know whether or not in this time</p> <p>15 frame Dr. Bailey had spoken to anybody at the FDA?</p> <p>16 A I'm not aware that he had.</p> <p>17 Q And you've never taken the time</p> <p>18 before -- before today, and we've had -- this is</p> <p>19 the second day of deposition. You've had</p> <p>20 depositions in other cases. You've never spoken</p> <p>21 to him about this issue?</p> <p>22 A No.</p> <p>23 MR. LOCKE: You're welcome to show her a</p> <p>24 document if it -- can refresh her recollection.</p> <p>25 MR. TISI: I'm sure I know the rules,</p>	<p>1 representative of PCPC, you agree with everything</p> <p>2 that's in that document.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: What I'm saying is -- when</p> <p>5 you say "drafted by somebody else," I mean it was</p> <p>6 drafted by epidemiologists. So --</p> <p>7 BY MR. TISI:</p> <p>8 Q Right. With the input of Imerys and</p> <p>9 J&J, correct?</p> <p>10 A Well, I think -- I mean they're speaking</p> <p>11 for themselves.</p> <p>12 Q But -- but --</p> <p>13 A I take that at face value.</p> <p>14 Q But the report was actually --</p> <p>15 MR. LOCKE: Let her finish her answer,</p> <p>16 please.</p> <p>17 BY MR. TISI:</p> <p>18 Q You don't know what happened at the</p> <p>19 meeting in -- in November when -- when Dr. Muscat</p> <p>20 and Huncharek went to Skillman, New Jersey, and</p> <p>21 met with J&J and Imerys, correct?</p> <p>22 A Because I wasn't there. I mean, I can</p> <p>23 read the -- the submission. So --</p> <p>24 Q Right. And you don't know what edits</p> <p>25 were made to the original document, do you?</p>

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<p style="text-align: right;">Page 528</p> <p>1 MS. FRAZIER: Object to form. 2 THE WITNESS: No. 3 BY MR. TISI: 4 Q And when a -- when a company -- I mean, 5 when a company commissions a report like this, 6 doesn't the company usually reserve the right to 7 review it and make comments and edits before it's 8 submitted? 9 MR. LOCKE: Objection. Beyond the 10 scope. 11 BY MR. TISI: 12 Q Typically? 13 A I mean that -- 14 MR. LOCKE: Objection. 15 THE WITNESS: -- that brings up like us 16 doing that, PCPC, you know, talc, other topics, 17 whatever, and yes, but I think when you're hiring 18 reputable people, they're not going to let you 19 change their conclusions. I mean, you might have 20 edits, typos, clarity needed. I mean... 21 BY MR. TISI: 22 Q Right. Focus. 23 A Yeah. 24 Q Right. But -- but -- I mean that 25 presumes that these are reputable people in part,</p>	<p style="text-align: right;">Page 530</p> <p>1 that says "Meta-Analysis Research Group" across 2 the top, right? 3 A Yes. 4 Q Okay. Did you do any due diligence as 5 to -- as to who Meta-Analysis Research Group was? 6 MR. LOCKE: Objection. Asked and 7 answered. 8 THE WITNESS: We put faith in the 9 epidemiologists as knowledgeable epidemiologists. 10 BY MR. TISI: 11 Q Okay. Without doing your due diligence. 12 MR. LOCKE: Objection. 13 BY MR. TISI: 14 Q You did not investigate Dr. Huncharek 15 and Muscat and what their relationship was, where 16 their funding came from, and how much time they 17 spent on these issues, did you? 18 MR. LOCKE: Objection. Mischaracterizes 19 testimony, asked and answered. 20 THE WITNESS: We accepted them because 21 of their epidemiology expertise. 22 BY MR. TISI: 23 Q Did you have an opportunity to review 24 this before it went in? 25 A As I say, I'm sure I did.</p>
<p style="text-align: right;">Page 529</p> <p>1 don't you think? 2 MR. LOCKE: Objection. 3 THE WITNESS: It does. 4 BY MR. TISI: 5 Q Did you -- did you do -- I mean that's 6 why I brought the brochure out there. You didn't 7 do any due diligence as to who these people were 8 and what their stake was in this issue, did you? 9 MR. LOCKE: Objection. Mischaracterizes 10 testimony. 11 THE WITNESS: Yeah. 12 MR. TISI: Whose testimony? 13 MR. LOCKE: Hers. 14 BY MR. TISI: 15 Q Did you do any due diligence into who 16 Meta-Analysis Research Group is and to where they 17 got their major funding? 18 MR. LOCKE: Objection. Asked and 19 answered. We've covered this. 20 BY MR. TISI: 21 Q Did you do it? 22 A We had worked with Dr. Muscat before. 23 Q I -- I didn't ask you that question. 24 This was written on behalf of Meta-Analysis 25 Research Group, correct? It's got the big logo</p>	<p style="text-align: right;">Page 531</p> <p>1 Q Okay. Have you had any -- do you have 2 any dispute that this is PCPC's response, that 3 PCPC agrees with the content? 4 MR. LOCKE: Objection. Asked and 5 answered. The witness testified it was submitted 6 by the two epidemiologists. 7 MR. TISI: I -- I'm not going to ask you 8 to characterize it. Your not under oath, Counsel. 9 I appreciate you schooling me, but honestly. 10 BY MR. TISI: 11 Q Is this PCPC's document? 12 MR. LOCKE: We're just going to stick 13 with the prior answer then. 14 BY MR. TISI: 15 Q Is this PCPC's document? 16 MR. LOCKE: Objection. Asked and 17 answered. Let's move on. 18 MR. TISI: No, we're not moving on. I 19 want an answer to that question. 20 MR. LOCKE: You've answered -- she's 21 answered it three times. 22 BY MR. TISI: 23 Q Do you -- do you -- is this PCPC's -- I 24 mean, for example, we read a sentence at the very 25 beginning in the Introduction section that says,</p>

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<p style="text-align: right;">Page 532</p> <p>1 We --</p> <p>2 MR. LOCKE: You're talking about the</p> <p>3 instruction that was written by the two</p> <p>4 scientists?</p> <p>5 MR. TISI: The -- I don't know if that's</p> <p>6 written by the two scientists. That's my</p> <p>7 question.</p> <p>8 MR. LOCKE: Well, it says "prepared" --</p> <p>9 MR. TISI: Honestly, Counsel.</p> <p>10 MR. LOCKE: No, honestly.</p> <p>11 MR. TISI: Honestly, I'm asking the</p> <p>12 question. Okay. There's been a lot of</p> <p>13 ghostwriting in this case.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 BY MR. TISI:</p> <p>16 Q "Given the multiple implications of such</p> <p>17 warnings, the Personal Care Products Council</p> <p>18 sought an evaluation of the validity of the</p> <p>19 scientific facts underlying this request." Right?</p> <p>20 Do you know whether or not this</p> <p>21 document, Exhibit No. 20 -- 43, is the report</p> <p>22 submitted by PCPC and it is PCPC's position,</p> <p>23 correct?</p> <p>24 MR. LOCKE: Objection. Compound</p> <p>25 question.</p>	<p style="text-align: right;">Page 534</p> <p>1 Q Not a hundred percent consistent, but</p> <p>2 is --</p> <p>3 A But, yes.</p> <p>4 Q -- is a hundred percent consistency</p> <p>5 required?</p> <p>6 A No.</p> <p>7 Q Okay. So there was consistency across</p> <p>8 studies.</p> <p>9 Now, arguing against causal association,</p> <p>10 Dr. Bailey, on behalf of the PCPC, which you are</p> <p>11 here for --</p> <p>12 A Yes.</p> <p>13 Q -- says: "There is a lack of a clear</p> <p>14 dose-response relationship." Correct?</p> <p>15 A Yes.</p> <p>16 Q And even posits that some epidemiologic</p> <p>17 studies suggest an inverse association. Correct?</p> <p>18 A Correct.</p> <p>19 Q Now, as a toxicologist, if you see an</p> <p>20 inverse association with the disease, doesn't it</p> <p>21 raise the suggestion that this is a protective --</p> <p>22 may have a protective effect?</p> <p>23 MR. LOCKE: Objection. Beyond the</p> <p>24 scope, calls for expert testimony.</p> <p>25 BY MR. TISI:</p>
<p style="text-align: right;">Page 533</p> <p>1 THE WITNESS: I believe this is the</p> <p>2 document we submitted.</p> <p>3 BY MR. TISI:</p> <p>4 Q Okay. All right. Let's talk about it</p> <p>5 for a moment.</p> <p>6 The summary provided by Dr. Bailey in</p> <p>7 the cover letter says: "The review concludes that</p> <p>8 the weak epidemiologic association is unlikely to</p> <p>9 be causal."</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 MR. LOCKE: What page are you at?</p> <p>13 MR. TISI: Page 2, Dr. Bailey's letter.</p> <p>14 MR. LOCKE: Okay.</p> <p>15 BY MR. TISI:</p> <p>16 Q Putting aside the characterization of</p> <p>17 "weak," which we can talk about in a moment, do</p> <p>18 you believe that there was an epidemiologic</p> <p>19 association seen across studies?</p> <p>20 A It's not --</p> <p>21 MR. LOCKE: Objection. Beyond the</p> <p>22 scope.</p> <p>23 THE WITNESS: Not a hundred percent</p> <p>24 consistent, no.</p> <p>25 BY MR. TISI:</p>	<p style="text-align: right;">Page 535</p> <p>1 Q I mean there might be reasons why</p> <p>2 that -- why that is seen, correct?</p> <p>3 MR. LOCKE: Same objection.</p> <p>4 THE WITNESS: In theory, that's possible</p> <p>5 if there's consistency.</p> <p>6 BY MR. TISI:</p> <p>7 Q I mean if this was a protective of</p> <p>8 ovarian cancer, you may have found a miracle,</p> <p>9 right?</p> <p>10 A Well, I would go into the causality. It</p> <p>11 would work the same way for protective effect.</p> <p>12 Q You didn't believe that there was an</p> <p>13 inverse -- there was an inverse relationship</p> <p>14 between ovarian cancer and talc, did you?</p> <p>15 A That's not what it says. Some</p> <p>16 studies --</p> <p>17 Q Suggest that.</p> <p>18 A -- showed that.</p> <p>19 Q And if that were really something that</p> <p>20 was seen in some studies, as a toxicologist and as</p> <p>21 somebody who represents the talc industry, that</p> <p>22 would be something that would be really an</p> <p>23 interest to you, wouldn't it?</p> <p>24 A I don't read it that way at all. The</p> <p>25 point of saying that some studies showed an</p>

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<p>1 inverse relationship cast doubt on the causality.</p> <p>2 Q Okay. Well, there are biases that might</p> <p>3 suggest that -- why that would occur particularly</p> <p>4 with a disease like cancer. Are you familiar with</p> <p>5 survival bias? Have you ever heard of that?</p> <p>6 MR. LOCKE: Objection. Beyond the</p> <p>7 scope.</p> <p>8 THE WITNESS: I'm not sure what that</p> <p>9 phrase means.</p> <p>10 BY MR. TISI:</p> <p>11 Q Okay. Did you ever -- on behalf of the</p> <p>12 PCPC, did you ever ask whether or not there would</p> <p>13 be explanations consistent with causation by which</p> <p>14 you might see an inverse dose-response</p> <p>15 relationship?</p> <p>16 A I think -- I mean, as far as the</p> <p>17 scientist- -- the scientific analysis we left to</p> <p>18 the epidemiologists.</p> <p>19 Q Well, I mean, pardon me for being -- for</p> <p>20 being direct about this.</p> <p>21 Before this was actually filed, you and</p> <p>22 all of these -- these companies marched into the</p> <p>23 FDA on the Citizen's Petition issue on May -- in</p> <p>24 May of 2009 to talk about the epidemiology in</p> <p>25 part. Correct?</p>	<p>1 Q -- that are different than the</p> <p>2 explanation that Drs. Muscat and Huncharek said on</p> <p>3 the -- on behalf of the industry.</p> <p>4 A I think our --</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: I think our comments were</p> <p>7 posted, though, so somebody could see that they</p> <p>8 were --</p> <p>9 BY MR. TISI:</p> <p>10 Q Do you know whether or not Dr. Epstein</p> <p>11 or anybody else was contacted and say, These</p> <p>12 are -- these are the contacts. Do you want to</p> <p>13 respond? Do you know whether they even checked</p> <p>14 the website?</p> <p>15 A Well, I don't, but they had the right to</p> <p>16 check -- I mean --</p> <p>17 Q Right.</p> <p>18 A -- the same way as a Citizen Petition</p> <p>19 would be posted, the comments received would be</p> <p>20 posted.</p> <p>21 Q But not everybody has a former director</p> <p>22 of the division that considers this work for them</p> <p>23 like you did, correct?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 BY MR. TISI:</p>
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<p>1 A I think the talk on that was fairly</p> <p>2 limited. I mean, the parts I remember from that</p> <p>3 meeting had more to do with talking about sourcing</p> <p>4 and that sort of thing. I -- and again, as -- as</p> <p>5 the meeting minutes say, FDA wasn't engaging us in</p> <p>6 discussion. They were going to let us say our</p> <p>7 piece --</p> <p>8 Q Right.</p> <p>9 A -- and then said, Please submit that so</p> <p>10 that we can actually read and consider it.</p> <p>11 Q And there was no opportunity for</p> <p>12 doctor -- Dr. Epstein or anybody else to come in</p> <p>13 and say, You know, okay, we saw that in the -- in</p> <p>14 the medical literature. This is a possible</p> <p>15 explanation as to why that is.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 BY MR. TISI:</p> <p>18 Q There was no other opportunity in the</p> <p>19 four years that this was pending for -- for</p> <p>20 anybody to come in and say -- and say, You know</p> <p>21 what, we -- we noted that there's an inverse</p> <p>22 relationship, but these are possible explanations</p> <p>23 for that --</p> <p>24 MR. LOCKE: Objection.</p> <p>25 BY MR. TISI:</p>	<p>1 Q Do you know whether or not Epstein had</p> <p>2 any connection with the FDA?</p> <p>3 I mean, you have to admit having</p> <p>4 Dr. Bailey is a pretty -- is a pretty important</p> <p>5 connection to the FDA, don't you think?</p> <p>6 MR. LOCKE: Stop. Which question do you</p> <p>7 want her to answer?</p> <p>8 MR. TISI: That one.</p> <p>9 BY MR. TISI:</p> <p>10 Q That's a pretty important connection to</p> <p>11 the FDA, having somebody who worked for the</p> <p>12 division, correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, I think as I said</p> <p>15 before, he was -- he was hired for his</p> <p>16 understanding of the FDA, for his experience.</p> <p>17 BY MR. TISI:</p> <p>18 Q Not his contacts?</p> <p>19 A For knowing the people, that's -- that's</p> <p>20 okay. That doesn't mean they're going to --</p> <p>21 Q Right.</p> <p>22 A -- do things differently because they</p> <p>23 know the guy.</p> <p>24 Q Do you know -- do you know whether or</p> <p>25 not Dr. Epstein's group had any similar</p>

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<p>1 relationship with the FDA?</p> <p>2 A I -- I do not.</p> <p>3 Q So the next thing that Dr. Bailey on</p> <p>4 behalf of the PCPC says that: A plausible</p> <p>5 econom- -- biologic mechanism is lacking to</p> <p>6 explain a causal relationship."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q It talks about potential confounding</p> <p>10 factors, correct?</p> <p>11 A Yes.</p> <p>12 Q And it talks about -- summarizes all</p> <p>13 of -- all of the issues?</p> <p>14 A Yes.</p> <p>15 Q All right. Now, one of the things that</p> <p>16 the FDA was very concerned about at the meeting</p> <p>17 that you attended with them was whether or not</p> <p>18 cosmetic talc --</p> <p>19 The stuff that comes in the bottle,</p> <p>20 right?</p> <p>21 A Yes.</p> <p>22 Q -- had constituents that might explain</p> <p>23 the increased relative risks. They talk about</p> <p>24 asbestos, correct -- for example, correct?</p> <p>25 A I think they talked about purity, yes.</p>	<p>1 "An additional limitation on existing literature</p> <p>2 with the proposed talc/ovarian cancer association</p> <p>3 is a lack of any known biological mechanism."</p> <p>4 Do you see that?</p> <p>5 A I'm sorry. Okay. Now I'm -- on the</p> <p>6 right paragraph, I think. Yes.</p> <p>7 Q Okay. Next paragraph down, and feel</p> <p>8 free to read it if you wish. I'm not -- I assume</p> <p>9 you read this before you came in here today,</p> <p>10 right?</p> <p>11 A Yes.</p> <p>12 Q Okay. "He makes the point that</p> <p>13 initially Cramer, et al.," -- and that's</p> <p>14 Dr. Cramer we talked about before who published</p> <p>15 epidemiology -- several epidemiology studies, in</p> <p>16 fact, right?</p> <p>17 A Yes.</p> <p>18 Q He's one of the people who looked at the</p> <p>19 medical literature and thought there was a causal</p> <p>20 inference, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Okay.</p> <p>25 -- "and sought to draw an analogy</p>
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<p>1 Q Okay. And -- and that's an important</p> <p>2 issue, don't you think?</p> <p>3 A Sure.</p> <p>4 Q And one of the things that has made the</p> <p>5 points that is made by Dr. Bailey on behalf of the</p> <p>6 PCPC and Dr. Muscat and Huncharek is that there</p> <p>7 was no biologically plausible mechanism because</p> <p>8 talc is not known to be a carcinogen, pure talc.</p> <p>9 A Okay.</p> <p>10 Q Is that true? I mean, I could point it</p> <p>11 out. Let's go to the page -- let's go. Go to</p> <p>12 page 25 of the -- of Dr. Huncharek's report --</p> <p>13 Muscat and Huncharek's report.</p> <p>14 A Okay.</p> <p>15 Q Could you read -- let's put up the last</p> <p>16 two paragraphs.</p> <p>17 Are you there? It's page 25 of -- 28 of</p> <p>18 39.</p> <p>19 Okay. Now it says here: "Initially</p> <p>20 Cramer," and that's --</p> <p>21 A What page are you on?</p> <p>22 Q Page 20 -- it's 25 on the top. It says</p> <p>23 28 of 39.</p> <p>24 A 28. Okay. Got it.</p> <p>25 Q And the third paragraph down, it says:</p>	<p>1 between talc and fibrous asbestos, the latter</p> <p>2 being a known and well-described carcinogen."</p> <p>3 First of all, that's true, right?</p> <p>4 A I'm sorry. I'm --</p> <p>5 MR. LOCKE: What's your question?</p> <p>6 BY MR. TISI:</p> <p>7 Q I said -- I said asbestos -- "fibrous</p> <p>8 asbestos is a known and well-described</p> <p>9 carcinogen."</p> <p>10 A Where does it say that?</p> <p>11 Q First sentence, the last full paragraph</p> <p>12 starting "Initially."</p> <p>13 A Okay. Oh, okay it. Got it. Sorry.</p> <p>14 Very first sentence.</p> <p>15 Q And you agree with that, right, because</p> <p>16 you sent that --</p> <p>17 A Yes.</p> <p>18 Q -- on behalf of the PCPC? Okay.</p> <p>19 And he makes the point at the end that:</p> <p>20 "Prior to the 1970s, some products may have</p> <p>21 contained some asbestos." Correct?</p> <p>22 A Correct.</p> <p>23 Q And that's an argument you've heard over</p> <p>24 and over and over again, right?</p> <p>25 A Yes.</p>

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<p>1 Q Okay. And it says: "Clearly such 2 products could possibly represent a carcinogenic 3 risk secondary to asbestos contamination." 4 Correct? 5 A That's what it says. 6 Q Okay. And so we can agree that asbestos 7 contamination could in fact be a basis of talcum 8 powder products -- a biologically plausible 9 mechanism by which talcum powder products may 10 cause ovarian cancer. Correct? 11 MR. LOCKE: Objection. Beyond the 12 scope. 13 THE WITNESS: Yeah, I mean, I think what 14 this is actually saying is -- is that's not talc 15 per se. 16 BY MR. TISI: 17 Q Right. But we're talking about -- 18 that's why I made the point in the very beginning 19 of saying that -- we're talking about what's in 20 the bottle, right? 21 A Right. 22 Q And so if talcum powder products have 23 asbestos in it, that would be a biologically 24 plausible mechanism, and Drs. Huncharek and Muscat 25 assumed that there was none. That was a predicate</p>	<p>1 BY MR. TISI: 2 Q Okay. No detectable asbestos or no 3 asbestos? 4 A I mean, there is a specification that's 5 no detectable. 6 Q Different question. 7 My question is, are you representing to 8 the -- is this being represented to the FDA that 9 there is -- that asbestos was eliminated? 10 A I mean, I think the FDA knows as much 11 about what's going on with asbestos because they 12 were involved in the -- in the specification 13 that -- 14 Q In the 1970s? 15 MR. LOCKE: Let her -- 16 THE WITNESS: And understand there was a 17 detection limit. 18 BY MR. TISI: 19 Q Honestly, that -- that's not my 20 question. Okay? 21 MR. LOCKE: Let her finish her answer, 22 and then you can ask -- 23 BY MR. TISI: 24 Q My question -- my question is this -- 25 this report assumes that asbestos had been</p>
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<p>1 for their statement. 2 Because the next paragraph, it says: 3 "Since the early '70s, the relevant industries 4 voluntarily eliminated asbestos from contamination 5 from talc products." 6 Do you see that? 7 A Yes. 8 Q Okay. So the assumption being that 9 there was no asbestos that had been eliminated, 10 correct? 11 A That's what it says. 12 Q Okay. What does the word "elimination" 13 mean to you? 14 MR. LOCKE: Objection. 15 THE WITNESS: Well, it was the '70s when 16 the asbestos issue was raised, and there was a lot 17 of work by the industry to develop a specification 18 that -- that said that there would be no 19 detectable asbestos. 20 BY MR. TISI: 21 Q Right. And so the -- but my question 22 is, what does the word "elimination" mean to you? 23 MR. LOCKE: Objection. 24 THE WITNESS: I think in this context it 25 means no detectable asbestos.</p>	<p>1 eliminated from talcum powder products since 1970. 2 True or not true? 3 MR. LOCKE: Objection. 4 THE WITNESS: I -- I think it's like 5 anything else, at some detection limit. I mean 6 every contaminant has a detection limit. So I 7 think that's implied. 8 BY MR. TISI: 9 Q Okay. And if asbestos -- let's assume 10 that you use the right test, right? I mean, you 11 could use -- you could use a -- if you used the 12 wrong test and you don't -- it may go undetected, 13 right? 14 A Well, as is true for any analysis. 15 Q Correct. Okay. 16 So my quest- -- my question is when you 17 make the -- the statement does not say -- because 18 everybody had an opportunity to look at this 19 before it went in. 20 When this statement is made to the FDA, 21 it says asbestos had been eliminated. True? 22 A Again, I think you can argue what 23 that -- what that word -- what is meant by that 24 word here. 25 Q Okay. Well, we can agree that if there</p>

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<p>1 was some asbestos in some -- in talcum powder</p> <p>2 products, that would provide a biologically</p> <p>3 plausible mechanism which would explain the</p> <p>4 increased risk, right?</p> <p>5 MR. LOCKE: Objection. Beyond the</p> <p>6 scope.</p> <p>7 BY MR. TISI:</p> <p>8 Q And that's what the FDA was asking</p> <p>9 about, right?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q Because on the May 8th -- let me</p> <p>13 rephrase the question.</p> <p>14 On the May 8th meeting with -- with you</p> <p>15 all, and you made the point several times, in</p> <p>16 addition to the epidemiology, the FDA wanted to</p> <p>17 know just how pure talcum powder products were.</p> <p>18 A They wanted to know -- they raised</p> <p>19 questions about sourcing and testing and how do</p> <p>20 you find the mines and -- and that type of stuff.</p> <p>21 Q Because they wanted to know how -- well,</p> <p>22 you knew the -- the reason why they were asking</p> <p>23 that question because they wanted to know what was</p> <p>24 in the bottle.</p> <p>25 A Yes. They were trying to understand --</p>	<p>1 MS. FRAZIER: Object to form.</p> <p>2 BY MR. TISI:</p> <p>3 Q Did you know that?</p> <p>4 A I'm not sure what that means.</p> <p>5 Q Meaning that they had talc samples from</p> <p>6 the mines, from the -- from -- from -- that the</p> <p>7 grade of talc that was used in the talcum powder</p> <p>8 products to actual physical bottles that were</p> <p>9 returned by consumers.</p> <p>10 Did you know that?</p> <p>11 A I guess no, not really.</p> <p>12 Q I mean, one of the things -- if the FDA</p> <p>13 was asking you questions about whether or not what</p> <p>14 was in the bottle might contain things other than</p> <p>15 pure talc, were you curious as the entity to say,</p> <p>16 Hey, guys, do you have any samples around we can</p> <p>17 test?</p> <p>18 A I mean, I --</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: -- think we had -- we had</p> <p>21 worked with FDA and companies looking at that</p> <p>22 question, if we're talking about asbestos back in</p> <p>23 the '70s.</p> <p>24 BY MR. TISI:</p> <p>25 Q Right. And you also made the point that</p>
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<p>1 right.</p> <p>2 Q Right. This was not pharmaceutical</p> <p>3 grade talc. This was cosmetic talc, right?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I think it's basically the</p> <p>6 same as pharmaceutical grade talc, but yes.</p> <p>7 BY MR. TISI:</p> <p>8 Q But the point is there -- there are a</p> <p>9 lot of things -- so -- so what the FDA really</p> <p>10 wanted to drill down to here is -- I know you guys</p> <p>11 talked about, you know, talc as a molecule and</p> <p>12 whether or not it can cause ovarian cancer, and</p> <p>13 you addressed that issue, but are there other</p> <p>14 things in the bottle that might explain this</p> <p>15 increased risk? They asked you that question,</p> <p>16 right?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: And they asked us for</p> <p>19 follow-up information, which -- which we provided.</p> <p>20 BY MR. TISI:</p> <p>21 Q Now, one of the things we learned in</p> <p>22 this litigation is that these folks down here, the</p> <p>23 J&J and Imerys, had talc samples available to them</p> <p>24 for decades.</p> <p>25 MR. TISI: Objection.</p>	<p>1 some of those specifications were decades old,</p> <p>2 right? And one of the things that Dr. Bailey</p> <p>3 said, that they would be willing to look at -- at</p> <p>4 tightening up those specifications, right?</p> <p>5 MR. LOCKE: Objection.</p> <p>6 THE WITNESS: I think he did. I mean,</p> <p>7 there was always an openness -- obviously, FDA was</p> <p>8 welcome to do their own specification, but I don't</p> <p>9 think methodologies had substantially changed.</p> <p>10 BY MR. TISI:</p> <p>11 Q Well, do you know that?</p> <p>12 A Yes, actually, I think I could say I do.</p> <p>13 I think our specification is essentially the same</p> <p>14 as what the USP uses essentially. And I know like</p> <p>15 ASTM was looking at it, but they haven't changed</p> <p>16 anything or promulgated a new specification.</p> <p>17 Q So the question -- the question that I</p> <p>18 have here is, both the FDA and Dr. Bailey noted</p> <p>19 that the -- that the standards that were adopted</p> <p>20 in the 1970s were then decades old, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Noted where? At the</p> <p>23 meeting?</p> <p>24 BY MR. TISI:</p> <p>25 Q At the meeting. It says here -- if you</p>

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<p>1 go back to the meeting notes, it says --</p> <p>2 MR. LOCKE: Can you tell us which</p> <p>3 exhibit you're referring to?</p> <p>4 MR. TISI: Exhibit No. 55.</p> <p>5 BY MR. TISI:</p> <p>6 Q It says -- if you go to page 2, it says:</p> <p>7 "Dr. Bailey mentioned that the Council published</p> <p>8 specifications for talc as well as analytical</p> <p>9 methodology for asbestos. These are the ones most</p> <p>10 often cited for the raw material. He mentioned</p> <p>11 these were developed almost 20 -- 20 years ago,</p> <p>12 and that they would need to be checked for</p> <p>13 verifications."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q Okay. And so one of the things that the</p> <p>17 FDA and -- and the PCPC were talking about is, are</p> <p>18 our specifications for testing talc, are they</p> <p>19 outdated? Are they as stringent as they ought to</p> <p>20 be? Correct?</p> <p>21 MR. LOCKE: Object -- objection.</p> <p>22 THE WITNESS: That's what he's talking</p> <p>23 about here, yes, but he's certainly saying that we</p> <p>24 welcome FDA's --</p> <p>25 BY MR. TISI:</p>	<p>1 A -- and is used by USP.</p> <p>2 Q Did you go back and see whether or not</p> <p>3 there are other methods that would guarantee that</p> <p>4 asbestos had been eliminated -- well, let me</p> <p>5 rephrase the question for you.</p> <p>6 Is -- is it a -- would you agree with me</p> <p>7 that the goal here is to eliminate asbestos from</p> <p>8 cosmetic talc? You don't want any asbestos in</p> <p>9 cosmetic talc. Would you agree with that?</p> <p>10 A That's the ideal.</p> <p>11 Q That's the ideal.</p> <p>12 Particularly since this is a product</p> <p>13 that honestly there are other -- it's a cosmetic,</p> <p>14 and there are other alternatives out there, right?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: You don't need talc to</p> <p>17 live, yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q Right. And to the extent you do need it</p> <p>20 to live, there's corn starch, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: There's alternatives, yes.</p> <p>23 BY MR. TISI:</p> <p>24 Q Right. And so the question is, in light</p> <p>25 of that, you don't want any asbestos, none, zero.</p>
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<p>1 Q Of course.</p> <p>2 A -- to weigh in, and --</p> <p>3 Q Right. But the -- but the question is,</p> <p>4 when these specifications were -- were developed</p> <p>5 in the 1970s, the epidemiology studies hadn't come</p> <p>6 out yet, right? They didn't come out until 1982.</p> <p>7 You made it clear that it was the early 1980s.</p> <p>8 A That's true, yes.</p> <p>9 Q Okay. And so now you had a new</p> <p>10 potential risk that was really raised by the</p> <p>11 epidemiology studies, and one of the questions</p> <p>12 that you had to answer is, are those a</p> <p>13 biologically plausible mechanism, right?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. TISI:</p> <p>17 Q Okay. And in light of that, did you</p> <p>18 ever go back and say, Do we need to tighten up our</p> <p>19 standards and to use a different measurement that</p> <p>20 would make sure that we had, using your terms in</p> <p>21 here, "eliminated asbestos"?</p> <p>22 A I guess I'm just aware that basically</p> <p>23 the methods -- methodology used is still what is</p> <p>24 used today --</p> <p>25 Q Right.</p>	<p>1 You want it eliminated. True?</p> <p>2 A You want it to be very low. My</p> <p>3 understanding is the methodologies that are used,</p> <p>4 it's actually gotten lower in detection limits,</p> <p>5 and we are using what -- again, the equivalent of</p> <p>6 a USP method.</p> <p>7 Q Okay. All right. Now, let's talk about</p> <p>8 other aspects of this report, if we could.</p> <p>9 First of all, can you -- I asked you</p> <p>10 whether or not -- on the asbestos issue, whether</p> <p>11 or not the company had ever gone back and -- the</p> <p>12 companies that were the primary people here had</p> <p>13 ever gone back and actually tested samples that it</p> <p>14 had in its possession that went back decades, and</p> <p>15 you indicated you didn't even know they had them,</p> <p>16 right?</p> <p>17 A Right.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q Were you able to produce to the FDA any</p> <p>21 testing records, any -- any literature, any</p> <p>22 outside audit, anything, that went back and looked</p> <p>23 at talc being tested to demonstrate the</p> <p>24 truthfulness of what Drs. Huncharek and Muscat</p> <p>25 assumed, that asbestos had been eliminated? Or</p>

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<p style="text-align: right;">Page 556</p> <p>1 did you just make the statement?</p> <p>2 A I mean there was a great deal of testing</p> <p>3 that went on in the early '70s --</p> <p>4 Q Right.</p> <p>5 A -- to show it was not detectable, and</p> <p>6 that's what the specification says.</p> <p>7 Q Got you. From the 1970s. Now you're</p> <p>8 meeting with them in -- in May of 2008. They're</p> <p>9 asking you about asbestos. Right? So now we're</p> <p>10 the '70s, '80s, '90s, 2000s, it's almost 30 years.</p> <p>11 Between the 1970s and the 2000s, did you</p> <p>12 come forward, either on your behalf or did any of</p> <p>13 these companies come forward and say, Look, we're</p> <p>14 going to show you proof that our talc from the</p> <p>15 1970s forward did not have asbestos in it, or was</p> <p>16 that statement just made?</p> <p>17 A I think it -- the basis of the statement</p> <p>18 was, again, the work that had done -- been done in</p> <p>19 the '70s to set up the specification. It was the</p> <p>20 discussions that followed with FDA to talk -- to</p> <p>21 answer the questions about sourcing and testing.</p> <p>22 Q Agreed.</p> <p>23 A I think if you're taking "elimination"</p> <p>24 to mean a literal zero, I can't think of any</p> <p>25 contaminant that anybody can say is a literal</p>	<p style="text-align: right;">Page 558</p> <p>1 cetera. I mean, the --</p> <p>2 BY MR. TISI:</p> <p>3 Q Well, the FDA on the translocation issue</p> <p>4 said that that's definitely biologically</p> <p>5 plausible.</p> <p>6 A They did say that.</p> <p>7 Q Okay. So let's --</p> <p>8 A I'm not sure what their basis was</p> <p>9 because they didn't reference, but they did say</p> <p>10 that.</p> <p>11 Q Well, but you didn't reference proof</p> <p>12 that there was -- okay. Let's -- so let's be fair</p> <p>13 here. Okay.</p> <p>14 You say the FDA didn't -- didn't</p> <p>15 reference the support for a translocation. Fine.</p> <p>16 What is your reference that in the</p> <p>17 1980s, 1990s and 2000s, there was no contaminants</p> <p>18 in talc, talcum powder products, that were</p> <p>19 potentially biologically plausible mechanisms that</p> <p>20 would explain what we all agree is a trend towards</p> <p>21 an increased risk seen in the epidemiology</p> <p>22 studies?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I mean there was no</p> <p>25 evidence for talc itself. As I say, perfume</p>
<p style="text-align: right;">Page 557</p> <p>1 zero.</p> <p>2 Q So do you know -- did you take into</p> <p>3 account whether or not talcum -- talcum powder</p> <p>4 products have fragrances, right?</p> <p>5 A Yes.</p> <p>6 Q Did you look at the fragrances in there</p> <p>7 to see whether that provided a biologically</p> <p>8 plausible mechanism?</p> <p>9 MR. LOCKE: When you say "look" -- "did</p> <p>10 you look," are you referring --</p> <p>11 MR. TISI: PCPC.</p> <p>12 BY MR. TISI:</p> <p>13 Q Did PCPC, when it provided this report</p> <p>14 to the -- to the -- to the FDA talking about</p> <p>15 biologic plausibility, there's no way this</p> <p>16 happens, right? When you said that to the FDA,</p> <p>17 okay, did you consider whether or not what was in</p> <p>18 the bottle contained other things that might</p> <p>19 provide that mechanism?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I mean, I -- I think when</p> <p>22 you're talking about fragrance, which we -- is</p> <p>23 part of a lot of products, I mean, we do not think</p> <p>24 of fragrances as being carcinogenic, not to</p> <p>25 mention the whole thing about translocation, et</p>	<p style="text-align: right;">Page 559</p> <p>1 fragrance is not regarded --</p> <p>2 BY MR. TISI:</p> <p>3 Q You don't look at it.</p> <p>4 A -- as a carcinogen.</p> <p>5 Q You don't look at it. Did you?</p> <p>6 A We --</p> <p>7 Q Has there been a lot of discussion</p> <p>8 about -- let me --</p> <p>9 A Fragrance in general. I mean it's used</p> <p>10 in body lotion, it's used in -- as fragrance.</p> <p>11 It's used in --</p> <p>12 Q Right, but it doesn't -- it doesn't --</p> <p>13 A It's not considered carcinogenic.</p> <p>14 Q -- it doesn't -- but is body lotion,</p> <p>15 does that come in contact with your ovaries,</p> <p>16 typically? Are there any epidemiology -- are</p> <p>17 there any epidemiologies that's --</p> <p>18 A The components of fragrance are not</p> <p>19 regarded as --</p> <p>20 Q Did you look?</p> <p>21 A Look at?</p> <p>22 Q Every component that was in the bottle,</p> <p>23 did you look at each one of them and see whether</p> <p>24 or not there was things that could be in that</p> <p>25 bottle that provided a biologically plausible --</p>

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<p>1 or did you look solely at pure talc?</p> <p>2 A I guess the -- the main thing I think of</p> <p>3 is fragrance, and certainly we've been concerned</p> <p>4 with fragrance and have an understanding of what</p> <p>5 fragrance materials are, and --</p> <p>6 Q Do you know whether or not -- did -- did</p> <p>7 you ask them whether it contains nickel and</p> <p>8 chromium and silica or any of those other --</p> <p>9 talcum powder comes from the ground, right?</p> <p>10 A Yes.</p> <p>11 Q Okay. And those are things that are</p> <p>12 not -- that are not desirable in talc either,</p> <p>13 right?</p> <p>14 A Correct.</p> <p>15 Q Okay. So my question is, your whole</p> <p>16 premise for this opposition for Citizen's</p> <p>17 Petition -- Dr. Epstein wanted a warning on talcum</p> <p>18 powder products, which is everything in the</p> <p>19 bottle. Right?</p> <p>20 A Yes.</p> <p>21 Q Your response focused on talc. Correct?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: Which makes up the vast</p> <p>24 majority of the product.</p> <p>25 BY MR. TISI:</p>	<p>1 A If somebody wanted to address our</p> <p>2 arguments and disagree with them, they could do</p> <p>3 so.</p> <p>4 Q Okay. So let's talk about -- let's just</p> <p>5 go here, because I think this will be -- and then</p> <p>6 we'll just break for lunch. I think it's lunch.</p> <p>7 Yeah, we'll break for lunch.</p> <p>8 If you go to page -- if you go to</p> <p>9 page 21 of the Introduction.</p> <p>10 A This is 21 --</p> <p>11 Q I'm sorry, 24 of 39 if you're looking at</p> <p>12 the --</p> <p>13 A 24 of 39, okay.</p> <p>14 Q So at the very last, it talks about</p> <p>15 experimental studies and clinical trials. Do you</p> <p>16 see that?</p> <p>17 It says: "In the contest of human</p> <p>18 studies, experimental design has come to represent</p> <p>19 the gold standard of cause and effect relationship</p> <p>20 as the randomized clinical trial."</p> <p>21 A Yes.</p> <p>22 Q Okay. First of all, would you agree</p> <p>23 with me -- I mean, you've done this for a long</p> <p>24 time -- you would agree with me that it would be</p> <p>25 both unfeasible and unethical to conduct a</p>
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<p>1 Q The vast majority of the product but not</p> <p>2 all of the product. Correct?</p> <p>3 A I mean, we -- we have other lines of</p> <p>4 evidence, and our -- and -- and the arguments that</p> <p>5 we make are -- I mean, we're not alone in this.</p> <p>6 We're consistent that there is --</p> <p>7 Q I understand. But there are other</p> <p>8 people who think differently than you, right? You</p> <p>9 say you're not alone. There are other scientists</p> <p>10 who look at the evidence and think differently</p> <p>11 than you.</p> <p>12 A As -- as we've discussed.</p> <p>13 Q And they weren't in the room when you</p> <p>14 were discussing with the FDA, were they?</p> <p>15 A But, again, I -- I don't think we were</p> <p>16 even having --</p> <p>17 Q No, they were -- they were not in the</p> <p>18 room.</p> <p>19 MR. LOCKE: Let her finish the question.</p> <p>20 BY MR. TISI:</p> <p>21 Q They were not -- only you were in the</p> <p>22 room. And --</p> <p>23 A But we submitted this -- these are our</p> <p>24 arguments; they get posted on the website.</p> <p>25 Q Okay.</p>	<p>1 clinical trial where the hypothesis was, Let's</p> <p>2 give people talcum powder products and see whether</p> <p>3 it causes ovarian cancer.</p> <p>4 A Right. That's not how you do studies.</p> <p>5 Q You can't do it.</p> <p>6 A Right.</p> <p>7 Q So you can't -- so a clinical trial, if</p> <p>8 anyone were to kind of march on into court and</p> <p>9 say, You know, there were no clinical trials, you</p> <p>10 would expect to see clinical trials on this?</p> <p>11 A Correct. That's not how it's done.</p> <p>12 Q Right. So the next question is they</p> <p>13 have to rely on epidemiology research. Do you see</p> <p>14 that?</p> <p>15 A Yes.</p> <p>16 Q Okay. And they lay out a methodology</p> <p>17 here. It says: "An epidemiologist must observe</p> <p>18 observational methods to cause and effect</p> <p>19 relationship that preclude direct intervention on</p> <p>20 manipulation of study subjects."</p> <p>21 That's experiments, right?</p> <p>22 A Yes.</p> <p>23 Q All right. "Because of that fact,</p> <p>24 criteria for establishing cause and effect</p> <p>25 relationship are inherently different when</p>

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<p>1 utilizing epidemiologic methods versus 2 experimental ones." 3 Do you see that? 4 A Yes. 5 Q Okay. And so what they're saying is, 6 Look, you can't do a clinical trial because it's 7 unworkable, unethical. You just can't do it. So 8 you got to do it a different way. 9 A Yes. 10 Q Okay. And one of the ways that they do 11 it, they describe a -- a system or framework, 12 okay, and the framework is what we've called the 13 Bradford Hill criteria, and you've seen that 14 before? 15 A Yes. 16 Q And as somebody who's a scientist, 17 you're familiar with what that is? 18 A Yes. 19 Q Okay. And just to be clear, 20 Dr. Huncharek and Muscat make it clear, but I want 21 to make clear that from -- PCPC agrees with it as 22 well, these are criteria that are not really 23 criteria. They're -- they're considerations. 24 A They're -- right. Guidelines, I guess, 25 or -- right.</p>	<p>1 A I -- that's reasonable. 2 Q Okay. And that's not unusual in 3 science. Right? 4 A Correct. Scientists disagree. 5 Q I mean, for years there was a debate 6 about whether cigarette smoking causes cancer, 7 right? 8 MR. LOCKE: Objection. Beyond the 9 scope. 10 THE WITNESS: Yeah, before my time. I 11 think I've always known it, but yes. 12 BY MR. TISI: 13 Q Right. But you know that there was a 14 debate for decades on that question. 15 MR. LOCKE: Same objection. 16 THE WITNESS: I really don't. So... 17 BY MR. TISI: 18 Q You don't know that? 19 A No. 20 Q You must be much younger than me. 21 But you do know that -- that it is not 22 unusual for scientists to look at a question, 23 apply these factors, and come out with different 24 conclusions, correct? 25 A Yes.</p>
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<p>1 Q Right. They're not things where you 2 kind of -- it's not like a menu where you check 3 off, Okay, we got this one, we got that one, we 4 got this one, right? 5 A You use it for overall, right, 6 assessment. 7 Q Right. And they make that point. They 8 say: "The Hill criteria, as they've become known, 9 are not simply a checklist of requirements that 10 must be met in order to determine a cause and 11 effect relationship." 12 And that's true, right? 13 A Yes. 14 Q Okay. And so these factors, and I think 15 they have nine of them here, are factors that are 16 considered, correct? 17 A Yes. 18 Q And -- and kind of what we were talking 19 about before that I think is really important to 20 kind of -- why this has been a debate is because 21 different scientists looking at the evidence have 22 come to different conclusions about these 23 different factors. 24 A Okay. 25 Q Is that true?</p>	<p>1 Q And so these are not criteria so much, 2 these Hill factors, as they are a framework of 3 considerations. 4 MR. LOCKE: Objection. Beyond the 5 scope. 6 BY MR. TISI: 7 Q True? 8 A "Framework" is what it says here. 9 Q And you agree with that? 10 A Yes. 11 Q They also say something here that I -- 12 that I want to see whether you agree with and you 13 agreed with at the time. 14 On page 26 of 29 -- well, one of the 15 things they say here is -- actually, let's go 16 back. 17 It says: "Overview. The possibility 18 that perineal talc exposure could be associated 19 with the development of ovarian cancer was 20 initially derived from a case controlled study 21 published in 1982." 22 Do you see that? 23 A Yes. 24 Q It's under "Overview." 25 A Yeah, now I see it.</p>

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<p style="text-align: right;">Page 568</p> <p>1 Q "Since that time a number of additional 2 reports have addressed this question with most 3 showing odds ratio between 1.0 and 2.0." Correct? 4 A Yes. 5 Q Okay. That's -- that's between -- if we 6 were to -- and for jurors who don't understand 7 odds ratios, that's basically showing anything 8 from a 1 percent increase to 100 percent increase. 9 A Correct. 10 Q Okay. 2.0 would be a doubling of the 11 risk. 12 A Correct. 13 Q And that's what they call -- they call 14 this a weak effect. Correct? 15 A Yes. 16 Q So just using the nomenclature that 17 Dr. Muscat and Huncharek used, they would 18 characterize something less than a hundred percent 19 doubling of the risk as being weak. 20 A Per an epidemiology study, yes. 21 Q Right. But in practical reality, if you 22 find something that doubles your risk, that is a 23 clinically -- if it is a true cause, that's 24 clinically significant, correct? 25 A If it --</p>	<p style="text-align: right;">Page 570</p> <p>1 Q Do you agree with it? 2 MR. LOCKE: Objection. Beyond the 3 scope. 4 BY MR. TISI: 5 Q On behalf of PCPC, is that something 6 that PCPC agreed with when they sent this to the 7 FDA? 8 MR. LOCKE: Objection. Beyond the 9 scope. 10 THE WITNESS: We -- yes. 11 BY MR. TISI: 12 Q Thank you. 13 Did PC -- they note down here that 14 obviously -- actually, let's skip that. 15 MR. LOCKE: Is this a good time for a 16 lunch break? 17 MR. TISI: Yeah, it's a good time to 18 break. 19 THE VIDEOGRAPHER: The time is 20 12:32 p.m., and we're going off the record. 21 (Lunch recess.) 22 THE VIDEOGRAPHER: The time is 1:12 23 p.m., and we are back on the record. 24 BY MR. TISI: 25 Q Dr. Loretz, we were talking about the</p>
<p style="text-align: right;">Page 569</p> <p>1 MR. LOCKE: Objection. 2 THE WITNESS: -- is a true cause. 3 MR. LOCKE: Beyond the scope. 4 BY MR. LOCKE: 5 Q If it is a true cause. All right. 6 So now the question is, if you go to 7 page 23, they make the point, and they go out of 8 their way to make it, actually, because they say: 9 "It is important to point out that although an 10 association is weak" -- 11 MR. LOCKE: Just wait -- wait one 12 second. You're referring to 23 at the top -- 13 MR. TISI: I'm sorry. 26 of 39, 14 correct. 15 BY MR. TISI: 16 Q "It is important" -- it says on the 17 first full paragraph: "It is important to point 18 out that although an association is weak" -- and 19 as they define "weak," that can include a doubling 20 of the risk, right? 21 A Up to. 22 Q Right. 23 -- "this does not rule out a causal 24 connection." Do you agree with that? 25 A That's what it says.</p>	<p style="text-align: right;">Page 571</p> <p>1 purity of talcum powder products that -- that's in 2 the bottle, and distinguishing it from talc in the 3 mine and et cetera, and before we took a break. 4 Do you remember that -- 5 A Yes. 6 Q -- session? 7 I have a couple more questions about 8 that and the document, but before I do, the focus 9 of the PCPC response was to focus on the 10 carcinogenic -- carcinogenic -- I'm sorry, let me 11 say it again. 12 The focus of the biologic plausibility 13 aspect of Dr. Muscat and Huncharek's response was 14 focused on two things. Number one, that talcum 15 powder products had been asbestos-free since 16 1970s, it had been eliminated. 17 Do you remember that? 18 A Yes. 19 Q Okay. Number two is that pure talc did 20 not -- there was no evidence that pure talc was 21 a -- had a mechanism that would lend itself to the 22 suggestion that it was a cause of ovarian cancer. 23 Correct? 24 A Right. 25 Q Right. So you were looking at asbestos,</p>

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<p>1 not there anymore; and talc, not a problem.</p> <p>2 Right?</p> <p>3 A Yes.</p> <p>4 Q Okay. So -- but -- and we talked about</p> <p>5 the question about whether or not talc really was</p> <p>6 asbestos-free before the -- the break, and I'm not</p> <p>7 going to go back into that again, but that was an</p> <p>8 area of concern from the FDA's perspective, and</p> <p>9 they raised it at the May meeting, May 2009.</p> <p>10 A And -- and I'm sure -- we responded by</p> <p>11 letting them know that the testing that had been</p> <p>12 done and continued to be done.</p> <p>13 Q Correct. Using --</p> <p>14 A And their own testing as well that they</p> <p>15 did.</p> <p>16 Q Using the 12 -- we'll talk about that in</p> <p>17 a moment, but using the 20-year-old standards that</p> <p>18 Dr. Bailey mentioned that they would be willing to</p> <p>19 update.</p> <p>20 A Which --</p> <p>21 MR. LOCKE: Objection.</p> <p>22 BY MR. TISI:</p> <p>23 Q Correct?</p> <p>24 A Which they -- which, again, are not</p> <p>25 substantially different from what is used today</p>	<p>1 attention that there are potentially other</p> <p>2 components of talcum powder products, constituents</p> <p>3 of talcum powder products, that need to be</p> <p>4 considered when addressing the question as to</p> <p>5 whether or not talcum powder products are a</p> <p>6 potential cause of ovarian cancer?</p> <p>7 A Are you talking about constituent</p> <p>8 ingredients or are you talking about constituent</p> <p>9 impurities?</p> <p>10 Q Anything. Anything in the --</p> <p>11 A I mean --</p> <p>12 Q You know, honestly, and I'm trying to be</p> <p>13 -- I'm trying to be as expansive as I can in this</p> <p>14 question.</p> <p>15 What I'm saying is, if I go to Walmart</p> <p>16 and pull a bottle of talcum powder, Johnson's Baby</p> <p>17 Powder off the shelf, whether they're impurities</p> <p>18 or whether they're intended ingredients or</p> <p>19 whatever, there are other constituents in there</p> <p>20 that have to be considered in the algorithm of</p> <p>21 whether or not talcum powder products cause</p> <p>22 ovarian cancer. True?</p> <p>23 A There are impurities that are covered by</p> <p>24 the specification, for example.</p> <p>25 Q Right. But -- but so my -- my question,</p>
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<p>1 by, for example, USP.</p> <p>2 Q Okay. So we discussed asbestos and</p> <p>3 talc, and I started getting into the question, but</p> <p>4 you know what's in the bottle, it's not only</p> <p>5 asbestos and talc. Remember we started that</p> <p>6 discussion before the break.</p> <p>7 A Yes.</p> <p>8 Q Okay. And in fact, that had been</p> <p>9 brought to your attention long before this</p> <p>10 petition was filed that talcum powder products may</p> <p>11 contain things that might or might not be</p> <p>12 carcinogens.</p> <p>13 A Okay.</p> <p>14 Q Well, is that true?</p> <p>15 A I'm not sure what you're referring to.</p> <p>16 Q Well, I'm asking you that before I --</p> <p>17 A I mean in the specific --</p> <p>18 Q -- show you a document --</p> <p>19 A In the specification we have some limits</p> <p>20 set for a few other possible contaminants.</p> <p>21 Q Well, had it ever been brought to your</p> <p>22 attention that talcum -- you mentioned -- we</p> <p>23 talked about fragrances, we talked about other</p> <p>24 things.</p> <p>25 Had it ever been brought to your</p>	<p>1 and I'm probably being inartful, so let me see if</p> <p>2 I can phrase it.</p> <p>3 We've previously discussed talcum powder</p> <p>4 products as kind of this two-dimensional thing,</p> <p>5 either it has asbestos or it doesn't have</p> <p>6 asbestos. Right? So --</p> <p>7 A Okay.</p> <p>8 Q So I'm -- I'm kind of moving off that</p> <p>9 because it's not that simple, is it?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q The question about whether or not there</p> <p>13 is a biologically plausible mechanism by -- that</p> <p>14 would explain the epidemiology studies which</p> <p>15 showed, as Dr. Huncharek and Muscat point --</p> <p>16 pointed out, a risk between one and -- you know,</p> <p>17 and a hundred percent, right? One to two, what</p> <p>18 you say is called mild. The question should be</p> <p>19 looked at comprehensively as to what is in the</p> <p>20 bottle.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 BY MR. TISI:</p> <p>23 Q Right?</p> <p>24 A Yes, I'm not aware of anything that --</p> <p>25 Q Well, did you look? I mean, the</p>

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<p>1 question is this -- this report that was sent to 2 the FDA takes a very elemental view of the 3 question. Prior to 1970, there was potential 4 contamination with asbestos. It went out, and 5 what's left is talc. 6 MR. LOCKE: Objection. 7 BY MR. TISI: 8 Q And talc doesn't cause cancer. That was 9 the essence of their argument, correct? 10 MR. LOCKE: Objection. 11 THE WITNESS: Well, no, I think there's 12 more in their arguments -- I mean -- 13 BY MR. TISI: 14 Q On the biologic plausibility issue, I 15 mean, they talked about dose-response and all that 16 stuff. But I'm talking about on the biologic 17 plausibility, on the question of whether there is 18 a -- an explanation that makes sense as to why 19 there's this persistent increased risk, they 20 looked basically at asbestos in talc. 21 MR. LOCKE: Objection. 22 THE WITNESS: Yeah, I'm not sure what -- 23 what other -- what else you wanted to be -- them 24 to address. 25 BY MR. TISI:</p>	<p>1 throw it at you. 2 BY MR. TISI: 3 Q I'm really going to only ask you about 4 the first page. 5 A Mm-hmm. 6 Q So just for the record, what this is, 7 this is a document from IMA Europe. What is IMA? 8 A Industrial Minerals Association. 9 Q So it's another trade group like the 10 PCPC? 11 A Correct. 12 Q Okay. It represents talc -- 13 A Mineral manufacturers, and talc is a 14 subset of that. 15 Q Okay. And it's to Dr. Muscat, correct? 16 A Yes. 17 Q Okay. Is this the same Dr. Muscat who 18 wrote the report a couple of years later for you? 19 A Yes. 20 Q Robert Glenn at Crowell & Moring. R. 21 Glenn. 22 A I'm sure it is there. I don't see it. 23 Q It's right after Joshua Muscat. 24 A Yep. Yes. 25 Q R. Glenn, Crowell & Moring, that's the</p>
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<p>1 Q Well, are there other things, either 2 contaminants or intended ingredients, that should 3 be factored into the equation that were not 4 addressed by their -- had -- let me rephrase the 5 question. And I'm sorry, I'm not being artful 6 here. 7 Are there other constituents within 8 cosmetic talc that should be -- should have been 9 considered on this biologically plausible 10 mechanism issue that were not? 11 A I -- I -- no, I'm not aware of -- 12 Q Okay. But no other constituents were in 13 fact considered, right? 14 A There's a specification that covers 15 some. 16 Q Okay. Were you ever made aware prior to 17 this time that there were other potential 18 constituents that had been classified as a 19 carcinogen other than asbestos? 20 A No. 21 Q I'm going to show you what I would like 22 to have marked as Exhibit No. 59. 23 (Exhibit No. 59 was marked for 24 identification.) 25 MR. TISI: I'm sorry, didn't mean to</p>	<p>1 lawyers for -- 2 A Yes. 3 Q -- they represent the lawyers for -- for 4 Imerys. 5 Linda Loretz is you? 6 A Yes. 7 Q Eric Turner, which is Luzenac, which is 8 Imerys? 9 A Yes. 10 Q Jocelyn Ferret, which is Luzenac -- 11 A Yes. 12 Q -- Imerys? 13 So -- and cc'd was Steve Mann for -- 14 from J&J. You see that? 15 A Yes. 16 Q And it's entitled "IARC, Dr. Huncharek 17 Comment." Do you see that? 18 A Yes. 19 Q Okay. And this is February 13th, 2006. 20 This was during the IARC proceedings? 21 A Okay. Yes. 22 Q Is that right? 23 A I would assume so, yes. 24 Q And it's an e-mail from IMA North 25 America to Joshua Muscat, who was the industry</p>

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<p>1 representative at IARC at the time.</p> <p>2 A Correct.</p> <p>3 Q Yes?</p> <p>4 A Yes.</p> <p>5 Q And it says: "What should be</p> <p>6 acknowledged is the difference between cosmetic</p> <p>7 talc grade, i.e., grade of talc, pure and</p> <p>8 extremely white, sold by talc producers at the</p> <p>9 gate of the mine" -- right?</p> <p>10 A Yes.</p> <p>11 Q -- "and cosmetic baby or body talc</p> <p>12 powder, i.e., loose powder manufactured by</p> <p>13 cosmetic manufacturers containing talc or corn</p> <p>14 starch, and also in the case of other minerals,</p> <p>15 kaolin, TiO₂, and all case additives such as</p> <p>16 perfumes and biocides, hexachlorophene in the</p> <p>17 past, a Category 3 IARC carcinogen" -- I won't</p> <p>18 even pronounce that -- imidazolidinyl urea" -- I</p> <p>19 don't know how to pronounce that -- "triclosan, et</p> <p>20 cetera. See documents sent by Jocelyn Ferret this</p> <p>21 morning."</p> <p>22 A Uh-huh.</p> <p>23 Q Okay. And the point that's being made</p> <p>24 here -- and, first of all, you got this. The</p> <p>25 point that's being made here is one of the things</p>	<p>1 When you filed your response to the</p> <p>2 Citizen's Petition, and addressed the issue of</p> <p>3 biologically plausible mechanisms, did you ask</p> <p>4 Dr. Muscat and Huncharek to look at each of the</p> <p>5 constituents in cosmetic talc sold in talcum</p> <p>6 powder products and see whether or not they</p> <p>7 individually or collectively might explain the</p> <p>8 increased risk?</p> <p>9 A I think the other ingredients that are</p> <p>10 used in talc are not carcinogenic.</p> <p>11 Q Well, did you -- what are the other</p> <p>12 talcs -- did you ask J&J to provide you with a</p> <p>13 list of -- list of products using talc?</p> <p>14 A List of ingredients used in talc?</p> <p>15 Q List of ingredients of talc.</p> <p>16 A No.</p> <p>17 Q Okay. So how do you know that none of</p> <p>18 them are carcinogenic?</p> <p>19 A We don't use carcinogens in cosmetics.</p> <p>20 Q You don't know what was in the talc that</p> <p>21 you were talking about with -- with the FDA, do</p> <p>22 you?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 BY MR. TISI:</p> <p>25 Q I mean -- I understand that</p>
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<p>1 that really ought to be considered when you're</p> <p>2 talking about talcum powder products and the risk</p> <p>3 of ovarian cancer, you need to think about not</p> <p>4 only what comes out of the mine but what's in the</p> <p>5 bottle.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 BY MR. TISI:</p> <p>8 Q Right?</p> <p>9 A Okay.</p> <p>10 Q Well, I mean, I'm asking you whether you</p> <p>11 agree with that or not.</p> <p>12 A I can agree with that without thinking</p> <p>13 that this explains anything.</p> <p>14 Q Okay.</p> <p>15 A Yes.</p> <p>16 Q Okay.</p> <p>17 A I mean you think about -- when you think</p> <p>18 about safety of a product --</p> <p>19 Q Well, I'll take it and I'll put it aside</p> <p>20 then.</p> <p>21 A No, I'm just saying when you think about</p> <p>22 safety of a product, you think about everything in</p> <p>23 the product. So...</p> <p>24 Q Well, that's right. And -- and that's</p> <p>25 kind of where I'm going here.</p>	<p>1 aspirationally you don't want to have</p> <p>2 carcinogen -- carcinogens in the talc that you</p> <p>3 sell to women who may use them to dust themselves.</p> <p>4 I -- I understand that that might be an</p> <p>5 aspiration.</p> <p>6 But in light of the fact that this issue</p> <p>7 had been pending for decades, and now was firmly</p> <p>8 before the FDA in the Citizen's Petition, do you</p> <p>9 think that it might have been prudent to identify,</p> <p>10 just as was identified in this document I showed</p> <p>11 you, Exhibit No. 59, what all the constituents are</p> <p>12 in order to do a searching analysis of whether or</p> <p>13 not there was something in the talc that might be</p> <p>14 responsible for this increased risk?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: I mean, I guess, you know,</p> <p>17 I can look at this, and I recognize these</p> <p>18 ingredients, and --</p> <p>19 BY MR. TISI:</p> <p>20 Q Well, these are some of them and there</p> <p>21 may be others. I mean you -- what about did you</p> <p>22 know how much silica was in the -- if any, was in</p> <p>23 the talcum?</p> <p>24 A There's specifications.</p> <p>25 Q I understand the specifications. Apart</p>

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<p>1 from the specifications, do you know how much 2 silica there was? 3 A No. 4 Q Do you know how much magnesium there 5 was? 6 A I'm not sure that's regarded as a 7 carcinogen. 8 Q What about nickel? 9 A I know there was at one point, there was 10 a report and it was our understanding, because 11 this is what we were told, that it was bound up in 12 the talc and not free nickel. 13 Q Well, who told you that? 14 A I think it was J&J. 15 Q Okay. What about -- what about 16 silica -- is nickel a carcinogen? 17 A I don't believe it's recognized as an 18 ovarian carcinogen, but I'm -- I'm not an expert 19 on nickel cariogenicity. 20 Q Okay. If there -- if there was nickel, 21 it would be something that you would want to look 22 at, right? 23 A I think it depends. 24 MR. LOCKE: Objection. 25 THE WITNESS: I mean --</p>	<p>1 constituents, right? 2 A I believe that's true. 3 Q And they did not talk about any of the 4 fragrance or any of the other issues that are in 5 there, correct? 6 A For the same reason. 7 Q Okay. Talk about cobalt? 8 A No. 9 Q Arsenic? 10 A There is a specification for arsenic. 11 Q Right. But saying something has a 12 specification does not mean that it's absent, 13 correct? 14 A Right. I mean there's a specification 15 set, I believe it's 3 parts -- I believe it's 3 16 parts per billion. 17 Q Right. 18 A So it could be up to that. 19 Q So when you say something meets 20 specifications, the specifications are only as 21 good as the sensitivity and specificity of the 22 test that's being used. 23 A Well, the specifications are designed to 24 set a level that would be acceptable, i.e., safe, 25 and the method that goes with that should be</p>
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<p>1 BY MR. TISI: 2 Q Well, my -- my larger point here, 3 Doctor -- and, you know, I don't want to belabor 4 the issue -- is when you responded to the FDA, the 5 Citizen's Petition, there is nothing in this 6 response that addresses the potential of any 7 contaminants in the product, even ones that meet 8 specifications. Is there? 9 MR. LOCKE: Are you referring solely to 10 biological plausibility? 11 BY MR. TISI: 12 Q On the biologic plausibility issue, 13 there's no discussion at all, nickel, chromium, 14 silica, asbestos to the extent that's in it since 15 the 1970s, there's no discussion of that, is 16 there? 17 A Because those weren't recognized as 18 being risks. Just as I state some of these are 19 not -- 20 Q Okay. And that's -- it was not part of 21 Dr. Huncharek and -- and Muscat's analysis to the 22 FDA, right? 23 MR. LOCKE: Objection. 24 BY MR. TISI: 25 Q They did not mention those other</p>	<p>1 designed to -- 2 Q And did -- 3 A -- test at that level. 4 Q And did you -- because you were involved 5 with working with those standards, right, and 6 helping develop those standards, right? 7 A Oh, no, that was before my time. 8 Q Okay. Well, I didn't mean you. I meant 9 PCPC. 10 A PCPC, yeah, absolutely. 11 Q I was putting the PCPC hat on. 12 A Okay. Sorry. Got it. 13 Q All of those specifications were 14 developed before the epidemiological studies on 15 ovarian cancer, true? 16 A Developed but then updated, post. 17 Q I guess my question is, did any of 18 those -- were any of those specifications, to your 19 knowledge, analyzed by PCPC in the context of 20 looking for biologically plausible mechanisms for 21 ovarian cancer? 22 A I guess I'd go back to, I can see a 23 listing here that it just -- 24 Q I didn't ask you that question. You 25 told me that you could answer the question without</p>

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<p>1 looking at that document.</p> <p>2 A Okay.</p> <p>3 Q So I'm not looking at that document.</p> <p>4 A Okay.</p> <p>5 Q My question is, did you -- did PCPC in</p> <p>6 the 2000s, while these epidemiological studies</p> <p>7 were being published, analyze the specifications</p> <p>8 for the elimination of these other constituents in</p> <p>9 light of those epidemiology -- epidemiological</p> <p>10 studies?</p> <p>11 A We -- no, we were not aware of other</p> <p>12 contaminants and/or ingredients that seemed to</p> <p>13 offer a biological plausible reason for the cause</p> <p>14 of ovarian cancer.</p> <p>15 Q Well, cobalt might, right? Did you look</p> <p>16 at the cobalt -- cobalt standards in connection</p> <p>17 with ovarian cancer -- your standards?</p> <p>18 A I was --</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: I would say we had no</p> <p>21 information that the cobalt contamination was a</p> <p>22 problem, and I'm not aware that cobalt has been</p> <p>23 implicated in ovarian cancer, although --</p> <p>24 BY MR. TISI:</p> <p>25 Q Arsenic.</p>	<p>1 quite here yet.</p> <p>2 A Okay.</p> <p>3 Q So we'll put it up on the screen and</p> <p>4 have it.</p> <p>5 Dr. Epstein had previously filed a</p> <p>6 Citizen's Petition before the FDA in the 1990s on</p> <p>7 this issue, correct?</p> <p>8 A Yes.</p> <p>9 Q And at that time who did that petition</p> <p>10 go to, do you know?</p> <p>11 A John Bailey, I believe.</p> <p>12 Q While he was at the FDA?</p> <p>13 A I believe so, yes.</p> <p>14 Q And did the FDA ever respond to that?</p> <p>15 A Yes, they rejected that petition.</p> <p>16 Q Well, didn't they -- didn't Dr. Bailey</p> <p>17 write a letter to Mr. -- to Dr. Epstein that</p> <p>18 said -- and we'll bring it up here.</p> <p>19 MR. TISI: Can we bring it up, please?</p> <p>20 MR. GOLOMB: I don't --</p> <p>21 MR. TISI: Well, we'll attach it as an</p> <p>22 exhibit. No, that's it. Oh, is that it? No --</p> <p>23 yeah.</p> <p>24 BY MR. TISI:</p> <p>25 Q The last -- it's dated July 21st, 1995,</p>
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<p>1 A -- I'm not an expert.</p> <p>2 Q Arsenic.</p> <p>3 A There's a specification for that.</p> <p>4 Q Did you analyze that specification in</p> <p>5 light of the -- the reported epidemiology results</p> <p>6 of ovarian cancer in talc?</p> <p>7 A I feel pretty comfortable saying that</p> <p>8 the specification would -- would be okay, and I'm</p> <p>9 not aware that arsenic has been implicated as an</p> <p>10 ovarian carcinogen.</p> <p>11 Q It didn't -- are they carcinogens?</p> <p>12 Would it be something that would have been to be</p> <p>13 looked at in light of the epidemiological studies?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: I'm not sure that offers a</p> <p>16 biologically plausible explanation.</p> <p>17 BY MR. TISI:</p> <p>18 Q So the fact that something -- okay.</p> <p>19 All right. One other question.</p> <p>20 (Counsel conferring.)</p> <p>21 Q All right. Let's go to Exhibit No. --</p> <p>22 okay.</p> <p>23 Now, I just want to go back to something</p> <p>24 I discussed earlier today and see if I can -- this</p> <p>25 was the document I was having printed. It's not</p>	<p>1 and that's Dr. Bailey who wrote that --</p> <p>2 MR. TISI: Can you make that --</p> <p>3 BY MR. TISI:</p> <p>4 Q -- and his response was --</p> <p>5 MR. TISI: Go the second paragraph,</p> <p>6 please.</p> <p>7 MR. GOLOMB: Second one?</p> <p>8 MR. TISI: Mm-hmm.</p> <p>9 BY MR. TISI:</p> <p>10 Q "The purpose of this is to advise you,</p> <p>11 in accordance with 21 CFR 10.30(e)(2), that we</p> <p>12 have not been able to reach a decision on your</p> <p>13 petition within the first 180 days of the filing</p> <p>14 of the petition because of limited availability of</p> <p>15 resources and other agency priorities."</p> <p>16 Is that accurate?</p> <p>17 A Yes.</p> <p>18 Q Okay. And this Citizen's Petition, the</p> <p>19 one we've been talking about all day, wasn't</p> <p>20 responded to for five years. Correct?</p> <p>21 A Yes.</p> <p>22 Q And that's the same division that</p> <p>23 considered the first one, right?</p> <p>24 A Well, I'm not sure when the response</p> <p>25 came to the first one. I mean the 180 days and</p>

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<p>1 that is -- I think it's pretty typical for 2 petitions that they, I believe, have some 3 obligation to respond, but that response can be to 4 say that we're not -- we're not done yet. 5 (Exhibit No. 60 was subsequently 6 marked for identification.) 7 BY MR. TISI: 8 Q Okay. I'm going to mark it as 9 Exhibit No. 60 when we get it. 10 So let me ask you this: I'm going to go 11 through each year, and I'm going to ask you, you 12 responded to the FDA questions that they asked 13 you, correct, at this May 9th -- 14 A Yes. 15 Q -- meeting? 16 Did PCPC in 2009, other than this 17 meeting, have any communications directly or 18 indirectly with FDA relating to asbestos in talc 19 other than responding to the questions? 20 A You can refresh my memory if there's 21 any. I -- I can't recall any. 22 Q This is -- you can't recall any. 23 2009, did PCPC have any direct or 24 indirect communications with FDA regarding the 25 issue of talc and ovarian cancer?</p>	<p>1 questions. 2 A Okay. 3 Q The first question is going to be 4 communications with the FDA on talc and ovarian 5 cancer association or risk. 6 And the second question is going to be 7 on specifications for talc, and particularly with 8 regard to asbestos. Okay? 9 So the first question, in 2010, do you 10 recall any question or any communications with FDA 11 regarding the issue of ovarian cancer and talc? 12 A I don't recall any, no. 13 Q Any communications with the FDA on any 14 specifications for issues relating to asbestos or 15 levels of asbestos in talc? 16 A Not that I recall. 17 Q Okay. 2011, same two questions. If you 18 want, I'll separate them out. 19 A I'm just trying to make sure I'm not 20 forgetting something. I don't recall, no. 21 Q 2012? 22 A And again, the question was on 23 asbestos -- 24 Q It was on the association between 25 ovarian cancer and talc or the asbestos levels or</p>
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<p>1 MR. LOCKE: Other than what we've 2 discussed? 3 MR. TISI: Other than what we -- I'm 4 sorry, I meant to say 2010. I'm sorry. 5 THE WITNESS: That's what I was confused 6 on. I was trying to -- 7 BY MR. TISI: 8 Q Yeah, I'm sorry. 9 A -- decide if you -- 10 Q Yeah. No, no, it was -- 11 A Okay. Got it. 12 Q It was a mistake. 13 A Okay. 14 Q Just to be clear, let me -- I'm going to 15 go through each year -- 16 A Okay. 17 Q -- and I want to find out what your 18 communications were in each year. 19 A That's what I thought you were doing. 20 Okay. 21 Q So 2010. 22 A I want to be careful not to forget 23 something. So the question was anything to do 24 with -- 25 Q Let's -- I want to ask you two separate</p>	<p>1 specifications for talc. 2 A And did you say meetings? 3 Q Any communications directly or 4 indirectly. 5 A I guess -- 6 Q I guess what I'm trying to do in kind of 7 a summary fashion is to ask you about any 8 communications. These are the ones that I've been 9 able to find. I found -- you know, I can go 10 through your answers -- 11 A Mm-hmm. 12 Q -- to the FDA questions and do that. 13 A Mm-hmm. 14 Q Other than that. 15 A Yeah, and I'm just trying to be careful 16 so I'm being -- being accurate. 17 Q Yeah. 18 A And I can say I'm not aware of any. I 19 know in 2000 -- when FDA, for example, did their 20 sampling plan, could someone in meeting with the 21 FDA on something else asked a question, how's it 22 going, you know, that's possible. But a meeting 23 specific to that or something -- some deep 24 discussions or work on a specification, not that 25 I'm aware of.</p>

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<p>1 Q Okay. Let me see if I can ask it this</p> <p>2 way, since we got through 2011.</p> <p>3 When is the next time, if ever, PCPC</p> <p>4 directly or indirectly spoke to the FDA about talc</p> <p>5 and ovarian cancer?</p> <p>6 A I'm just trying to think if I'm</p> <p>7 forgetting anything.</p> <p>8 I'm -- I'm not recalling. Again, there</p> <p>9 was the -- FDA did the assessment on the asbestos.</p> <p>10 There could have been conversations. I --</p> <p>11 Q Anything that you -- that you know of as</p> <p>12 you sit here right now, anything to -- and are</p> <p>13 prepared to testify to as a -- as a representative</p> <p>14 of PCPC?</p> <p>15 A Not that I can think of.</p> <p>16 Q Okay. When is the next time you talked</p> <p>17 about asbestos levels in talcum powder products or</p> <p>18 asbestos testing in talcum powder products, if</p> <p>19 ever?</p> <p>20 MR. LOCKE: With the FDA?</p> <p>21 MR. TISI: With the FDA.</p> <p>22 THE WITNESS: Oh, we're aware that FDA</p> <p>23 did their study, and we're aware, I mean, that our</p> <p>24 members test in a -- on an ongoing basis.</p> <p>25 BY MR. TISI:</p>	<p>1 discuss with your members whether you had a more</p> <p>2 fulsome survey that could be conducted either of</p> <p>3 currently marketed products or of, you know,</p> <p>4 samples that had been stored over time?</p> <p>5 A No, I think our answers -- when we</p> <p>6 answered FDA to their questions about testing, et</p> <p>7 cetera, I think -- I mean, that addressed it kind</p> <p>8 of in an ongoing way. So --</p> <p>9 Q Okay. You basically said, We tested it</p> <p>10 as we always did?</p> <p>11 A Yeah.</p> <p>12 Q So, as I understand it, from -- do you</p> <p>13 know who Susan Nicholson is from J&J?</p> <p>14 A Nettesheim?</p> <p>15 Q No, Nicholson.</p> <p>16 A Oh, no.</p> <p>17 Q I understand that J&J had a meeting with</p> <p>18 FDA in 2018. Do you know anything about that?</p> <p>19 A That would be this year.</p> <p>20 Q That would be this year.</p> <p>21 A No.</p> <p>22 Q Do you know of any communications that</p> <p>23 the company had with FDA about the lawsuits that</p> <p>24 have been pending and verdicts that have been</p> <p>25 obtained against the manufacturers of talc --</p>
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<p>1 Q Well, okay, let's -- since you raised</p> <p>2 that issue, FDA did a sampling of -- of certain</p> <p>3 products bought in the Washington, D.C. area, I</p> <p>4 think they said five out of nine, they -- there</p> <p>5 was -- that wasn't a study, was it? That wasn't a</p> <p>6 study, correct?</p> <p>7 A They -- they --</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: Yeah, that's not exactly</p> <p>10 what they did. They did -- I think they did from</p> <p>11 suppliers, and then they did 30-some products off</p> <p>12 the shelf.</p> <p>13 BY MR. TISI:</p> <p>14 Q Right. But they -- the FDA admitted</p> <p>15 that that was not a --</p> <p>16 A The FDA said it's not exhaustive.</p> <p>17 Q It's not -- they -- they went further</p> <p>18 than that. They said it was not -- they could not</p> <p>19 guarantee that this was a true sampling of talcum</p> <p>20 powder products out there, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: They said it was not --</p> <p>23 not a final answer, yes.</p> <p>24 BY MR. TISI:</p> <p>25 Q Right. And in that context, did you</p>	<p>1 A I do not.</p> <p>2 Q -- and talc products?</p> <p>3 MR. LOCKE: Well, just to clarify, when</p> <p>4 you say "the company," you're talking about J&J?</p> <p>5 MR. TISI: J&J.</p> <p>6 THE WITNESS: No.</p> <p>7 BY MR. TISI:</p> <p>8 Q Or -- or Imerys.</p> <p>9 Are you aware of any communications</p> <p>10 about the lawsuits that have --</p> <p>11 A That those companies have had with FDA?</p> <p>12 Q Yes.</p> <p>13 A No.</p> <p>14 Q Okay. So other -- the last meeting that</p> <p>15 you know of that you had that was formally or</p> <p>16 informally with the FDA on the issues of talcum</p> <p>17 powder products and ovarian cancer was in May of</p> <p>18 2008?</p> <p>19 MR. LOCKE: '9.</p> <p>20 THE WITNESS: '9.</p> <p>21 BY MR. TISI:</p> <p>22 Q '9. I'm doing what -- what Dr. Bailey</p> <p>23 did. Sorry.</p> <p>24 Just to be clear, the last time that</p> <p>25 you're aware of that PCPC had any direct contact</p>

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<p>1 with the FDA, either directly or indirectly, was</p> <p>2 the meeting in May of 2009, and any follow-up to</p> <p>3 that meeting that was requested by the FDA?</p> <p>4 A Something specific to that topic. As I</p> <p>5 say, it doesn't mean there weren't -- you know,</p> <p>6 when FDA unveiled their results about talc</p> <p>7 testing, it doesn't mean somebody didn't ask a</p> <p>8 question or whatever, but --</p> <p>9 Q Well, do you know of any questions they</p> <p>10 might have asked?</p> <p>11 A No, I don't.</p> <p>12 Q Okay. Okay.</p> <p>13 A But, I mean, we have FDA, for example,</p> <p>14 presents at kind of our meetings sometimes. I</p> <p>15 could see a question being asked. I just --</p> <p>16 Q But you don't know of any.</p> <p>17 A No, I do not.</p> <p>18 Q All right. So let's go to the second</p> <p>19 question, the second area that I said we would</p> <p>20 cover, which is studies and consultants.</p> <p>21 A Okay.</p> <p>22 Q I'm kind of done with the Citizens</p> <p>23 Petitions --</p> <p>24 A Okay.</p> <p>25 Q -- and contacts with the FDA issue.</p>	<p>1 A Correct.</p> <p>2 Q Now, if go to page 2, there's a section</p> <p>3 called "Manuscript Reviews." Do you see that?</p> <p>4 A Okay. Yes.</p> <p>5 Q And the second bullet point says: "The</p> <p>6 meta-analysis manuscript -- manuscript prepared by</p> <p>7 Dr. Gross, "and it has a number, "was discussed.</p> <p>8 It was agreed on the scientific content of the</p> <p>9 manuscript was good, but the format lacked</p> <p>10 clarity," and it goes on and on. Do you see that?</p> <p>11 A Yes.</p> <p>12 Q Okay. Are you familiar with the study</p> <p>13 by Dr. Gross?</p> <p>14 A I saw the manuscript in my preparation</p> <p>15 for this deposition.</p> <p>16 Q Now, I'm going to show you there was a</p> <p>17 published article by Gross and Berg. Have you</p> <p>18 seen that?</p> <p>19 A I think that sounds familiar.</p> <p>20 Q May I see --</p> <p>21 (Counsel conferring.)</p> <p>22 BY MR. TISI:</p> <p>23 Q Okay. I'm going to mark this as Exhibit</p> <p>24 No. 61, and I'm actually going to give you 62,</p> <p>25 which is I think the manuscript that you just may</p>
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<p>1 A Okay.</p> <p>2 Q Let's start in the 1990s. I'm going to</p> <p>3 go back to Exhibit No. 47, which is the notes from</p> <p>4 April 12th, 1994.</p> <p>5 A Okay.</p> <p>6 Q And that's the task force document.</p> <p>7 A Yes.</p> <p>8 Q And just -- you may have mentioned this</p> <p>9 the last time in your deposition, and I'm sorry,</p> <p>10 I'm trying not to retread old ground, but can you</p> <p>11 tell us what the task force was?</p> <p>12 A So this is the Talc Interested Party</p> <p>13 Task Force, so these are specifically people who</p> <p>14 have an interest in talc and are willing to pay</p> <p>15 for projects as well when required. And these are</p> <p>16 just the member companies, again, with an interest</p> <p>17 in the topic.</p> <p>18 Q Okay. And listed on this document are</p> <p>19 Johnson & Johnson, Luzenac, American Westminster,</p> <p>20 is that --</p> <p>21 A I don't know.</p> <p>22 Q I don't know that either.</p> <p>23 -- Procter & Gamble Company, Cosmair,</p> <p>24 Colgate Palmolive, Helene Curtis, and then CTFA,</p> <p>25 which is PCPC.</p>	<p>1 have referred to.</p> <p>2 (Exhibit Nos. 61 and 62 were</p> <p>3 marked for identification.)</p> <p>4 MR. TISI: Here is your copy. And here</p> <p>5 is 62.</p> <p>6 BY MR. TISI:</p> <p>7 Q Now, 61 is the published article,</p> <p>8 correct?</p> <p>9 A Yes.</p> <p>10 Q And 62 is the internal report, right?</p> <p>11 A Oh, I'm sorry. I haven't seen 62 yet.</p> <p>12 Yes.</p> <p>13 Q So one is titled -- the memorandum is</p> <p>14 entitled "Meta-Analysis." Right?</p> <p>15 A Yes.</p> <p>16 Q Okay. And you all paid, at least in</p> <p>17 part, for this, right?</p> <p>18 A I believe so, yes.</p> <p>19 Q And if you go to the back, the draft</p> <p>20 paper, the one that was not published, and you go</p> <p>21 to page 33, it says: "Financial support for this</p> <p>22 study was provided in part by the Cosmetic</p> <p>23 Toiletry and Fragrance Association."</p> <p>24 A Yes.</p> <p>25 Q Now --</p>

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<p>1 MR. GOLOMB: Wait, Chris, the document 2 is not up yet. 3 BY MR. TISI: 4 Q If you go to page -- 5 MR. GOLOMB: That's the wrong document. 6 MR. TISI: 62, yeah. 7 Yeah, that's right, go to the very end. 8 It's the Bates 188. 9 BY MR. TISI: 10 Q And the Acknowledgment section 11 acknowledges what I think you told us in your 12 interrogatories: "The financial support for this 13 study is provided in part by the Cosmetic, 14 Toiletry and Fragrance Association, correct? 15 A Yes. 16 Q Okay. Now, the report actually went 17 through peer review, right, and actually was 18 published? 19 A It looks that way, yes. 20 Q Yeah. And when it was published, did 21 you ask -- did PCPC ask that their name be taken 22 off the acknowledgment? Because they're not on 23 the acknowledgment of the published paper. 24 A I see that J&J is. 25 I -- I don't know what happened on that</p>	<p>1 A As we've discussed, yes. 2 Q And that reflects -- and if you go back 3 to my chart here, my -- my timeline, this reflects 4 the concerns that talcum powder products may cause 5 ovarian cancer, and there was an active debate 6 among scientists. That was the concept we talked 7 about earlier. 8 A Yes. 9 Q If you go to page -- 10 MR. TISI: I'm sorry? 11 (Counsel conferring.) 12 Q Okay. Let's go back to -- if you go to 13 page 192 of the study, the Discussion section. 14 A I'm sorry. Which one? 15 MR. LOCKE: 192. 16 THE WITNESS: I know. Which document? 17 BY MR. TISI: 18 Q The actual published study. 19 A Okay. 20 Q The authors -- and these are people who 21 were hired by -- paid for by you all, right? 22 A Again, I'm a little confused because it 23 says J&J. 24 Q Okay. But J&J was actually the -- you 25 know --</p>
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<p>1 funding. 2 Q Well, let's go to the published paper 3 and see what the published paper says. Okay? 4 A Mm-hmm. 5 Q The one that actually went through peer 6 review. Right? 7 A Yes. 8 Q Okay. First of all, and this -- so that 9 the jury understands, this is dated 1995. 10 A Okay. 11 Q This is some 10 -- 13 years before 12 the -- before the Citizen's Petition. 13 A Okay. 14 Q Right? 15 A Yes. 16 Q And so this is -- it says: "The concern 17 that use of talc or talc" -- this is the first 18 sentence of the abstract -- "the concern that use 19 of talc or talc-containing substances in the 20 perineal region of women may subject them to an 21 increased risk of ovarian cancer has become an 22 important issue in the study of ovarian cancer." 23 Is that -- did I read that correct? 24 A That's what it says, yes. 25 Q And that's true, right?</p>	<p>1 A Certainly part of, right, industry. 2 Q Right. So the discussion says: 3 "Existing evidence linking talc exposure to an 4 increased risk of ovarian cancer cannot be viewed 5 as scientifically conclusive based upon the 6 available epidemiological studies." Right? 7 A Mm-hmm. Yes. 8 Q Is it your view that the evidence must 9 be conclusive before women are told of the 10 potential risk in a cosmetic product? 11 MR. LOCKE: Objection. Beyond the scope 12 and to form. 13 BY MR. TISI: 14 Q You may answer the question. Must the 15 evidence be conclusive before women are told of 16 the potential risk? 17 MR. LOCKE: Same objection. 18 THE WITNESS: Yeah, I -- I -- 19 BY MR. TISI: 20 Q You know that the standard is that -- we 21 talked about this early on in the deposition -- 22 the standard is warnings should be added when 23 there may be a risk, correct? 24 MR. LOCKE: Objection. Beyond the scope 25 and form.</p>

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<p>1 BY MR. TISI: 2 Q You're told -- you know that, right? 3 MR. LOCKE: Same objection. 4 BY MR. TISI: 5 Q You actually publish -- PCPC publishes a 6 labeling book for its members, correct? 7 MR. LOCKE: Objection. 8 THE WITNESS: The labeling book deals 9 with current labeling requirements. 10 BY MR. TISI: 11 Q Right. And you know that warnings 12 should be added when there may be a risk, correct? 13 MR. LOCKE: Objection. Beyond the scope 14 and to form. 15 THE WITNESS: Yeah, that seems like a 16 legal labeling issue that's not anything -- 17 BY MR. TISI: 18 Q But you were responding to a Citizen's 19 Petition regarding labeling, right? You were 20 responding to that? 21 A We were responding to the science piece 22 of -- 23 Q Right. And I asked you what the 24 standard was because doctor -- Dr. Epstein was 25 asking for a label change. Right?</p>	<p>1 says: "However, all the meta-analysis arrive at a 2 relative risk rate of 1 with a 95 percent 3 confidence interval excluding the null." 4 That's basically saying that all the 5 meta-analysis done as of that time showed an 6 increased risk, correct? 7 MR. LOCKE: Objection. 8 THE WITNESS: Well, that's the 9 meta-analysis. That's not the individual studies. 10 BY MR. TISI: 11 Q The purpose of a meta-analysis is to 12 combine studies to increase the power of a study 13 to determine a risk, right? 14 MR. LOCKE: Objection. 15 THE WITNESS: I mean I'm not an 16 epidemiologist, but I would say, yes, that's their 17 basic purpose. 18 BY MR. TISI: 19 Q And the last page on page 193, and this 20 is of a 1995 article funded by you all. 21 MR. LOCKE: Objection. 22 THE WITNESS: Oh, yeah, it's -- I'm not 23 sure what happened here. The authors changed, the 24 things changed, and the -- the acknowledgments 25 changed. So I -- I don't want to say this was</p>
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<p>1 MR. LOCKE: You're asking her what you 2 asked her? 3 BY MR. TISI: 4 Q No, I -- you know that Dr. Epstein was 5 asking for a label change to add a warning about a 6 potential risk, right? 7 A I know that that's what he was asking 8 for, correct. 9 Q And you responded and opposed that, 10 correct? 11 MR. LOCKE: Objection. 12 THE WITNESS: Based on the science. 13 BY MR. TISI: 14 Q Right. And I asked you before, did you 15 know the standard, correct? 16 A And I think I said I didn't, that that 17 was a legal -- 18 Q Okay. And so you responded to the 19 petition not knowing what the standard was. 20 MR. LOCKE: Objection. 21 THE WITNESS: We responded by offering 22 scientific -- expert epidemiologists' opinion on 23 what the epidemiology shows. 24 BY MR. TISI: 25 Q Now, at the last sentence here, Dr. Berg</p>	<p>1 funded by PCPC. That's not what it says. And 2 there's definitely a change in authorship here, so 3 things changed. 4 BY MR. TISI: 5 Q The last sentence says: "The -- thus, 6 the body of knowledge found in the medical 7 literature does not unequivocally support the 8 hypothesis that talc use puts women at an 9 increased risk of ovarian cancer. However, the 10 results of this meta-analysis do suggest the 11 possibility of an increased ovarian cancer due to 12 peritoneal -- perineal talc use." 13 Do you see that? 14 A Yes. 15 Q And these were the same authors at least 16 that were the people that you all hired to do a 17 meta-analysis, correct? 18 A Well, I think we hired Dr. Gross, but I 19 don't think we hired Dr. Berg, so that's why I'm 20 saying I'm not sure. 21 Q And Dr. Berg -- Dr. Berg, I will 22 represent to you, was -- was a doctoral student of 23 Dr. Gross. And that's made clear in other 24 documents. 25 A Okay.</p>

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<p>1 Q He was basically given coauthorship, but</p> <p>2 it was really Dr. Gross.</p> <p>3 So can you say -- these appear to be the</p> <p>4 same. This one is March 17, 1994. This</p> <p>5 meta-analysis -- published meta-analysis is 1995.</p> <p>6 One says it's sponsored by J&J, the other one says</p> <p>7 CTFA.</p> <p>8 Do you agree that this is likely the</p> <p>9 same study?</p> <p>10 A I think it looks like it's related, yes.</p> <p>11 Q Okay. So this is one study that you</p> <p>12 authored -- that you were involved with.</p> <p>13 Let's go through another one.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 BY MR. TISI:</p> <p>16 Q Let's go back to the task force</p> <p>17 document. 1994.</p> <p>18 The last page, number 4 under the --</p> <p>19 this is under a heading entitled "Future Research</p> <p>20 Needs." Do you see that?</p> <p>21 A The last page?</p> <p>22 Q If you go to page --</p> <p>23 A I see "Future Research Needs."</p> <p>24 Q Right. And if you go to the last page,</p> <p>25 number 4.</p>	<p>1 that?</p> <p>2 A Yes.</p> <p>3 Q And at this time frame, as in others,</p> <p>4 this was an important issue, right? That's why</p> <p>5 you guys were meeting.</p> <p>6 A That's what we were talking about, yes.</p> <p>7 Q And other than the Berg article which we</p> <p>8 just discussed, are you aware of any industry-</p> <p>9 sponsored epidemiological study or meta-analysis</p> <p>10 that actually looked at the question specifically</p> <p>11 of whether ovarian cancer and talc were related?</p> <p>12 A Industry study, no.</p> <p>13 Q Given the importance of the issue, don't</p> <p>14 you find that a little odd?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q It was discussed, right, should we do a</p> <p>18 study?</p> <p>19 A Right. I don't know what the follow-up</p> <p>20 was, but, I mean, I guess the question is, is it</p> <p>21 going to make a difference and is it going to be</p> <p>22 criticized for being an industry study?</p> <p>23 Q Well, if the industry study found what</p> <p>24 everyone else said, then everyone would be on the</p> <p>25 same table, right? They would all -- everyone</p>
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<p>1 A Okay.</p> <p>2 Q Okay. Do you see that?</p> <p>3 A Yes.</p> <p>4 Q It says -- I don't know who MNordhauser</p> <p>5 is, but that seems to be a person, right?</p> <p>6 A I think it's Mary Ann Nordhauser.</p> <p>7 Q Okay. She pointed out: "The importance</p> <p>8 of considering other research directions in which</p> <p>9 the task force should be involved. Ms. Nordhauser</p> <p>10 suggested the task force consider sponsoring</p> <p>11 further epidemiological studies. It was noted</p> <p>12 that Dr. Ernst Wynder discussed an outline of such</p> <p>13 a research proposal at the IS RTP symposium. Mike</p> <p>14 Chudkowski agreed to discuss the developments of</p> <p>15 such a proposal with Dr. Wynder."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Okay. And was it important during the</p> <p>19 1990s for the CTFA and the members of the talc</p> <p>20 task force to do research into the area that we've</p> <p>21 been discussing, ovarian cancer and talc?</p> <p>22 A I guess I think it was discussed to see</p> <p>23 if -- you know --</p> <p>24 Q Well, she says: "The importance of</p> <p>25 considering research directions." Do you see</p>	<p>1 would all agree.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q Well, let me ask you this: Are you</p> <p>5 aware that Dr. Wynder did in fact propose a study?</p> <p>6 A I'm not aware.</p> <p>7 Q Do you know at the time you mentioned --</p> <p>8 now doctor -- who is Dr. Wynder?</p> <p>9 A I don't know.</p> <p>10 Q Do you know Dr. Wynder was with the</p> <p>11 American Health Foundation?</p> <p>12 A I guess I do now.</p> <p>13 Q You know the American Health Foundation</p> <p>14 was the same foundation where Dr. Muscat worked?</p> <p>15 A Yes.</p> <p>16 Q Do you know that Dr. Muscat proposed an</p> <p>17 epidemiology study to J&J to follow up exactly on</p> <p>18 this issue in 1994, 1995?</p> <p>19 A No, I don't know that. I mean, I</p> <p>20 believe that. I just don't know that.</p> <p>21 (Exhibit No. 63 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. TISI:</p> <p>24 Q I'm going to show you Exhibit No. 63.</p> <p>25 Now, I'll represent to you, because I</p>

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<p>1 don't like to misrepresent things, that the -- 2 that this is a composite exhibit. Okay. If you 3 notice the top is a grant application, but if you 4 notice the Bates numbers are -- don't coincide 5 directly with the attachment. 6 We discussed it with Dr. Muscat the 7 other day, so there is -- this was a -- he used a 8 grant application to Johnson & Johnson, but the 9 actual proposal is attached. 10 A Okay. 11 Q Okay? 12 A Yes. 13 Q And you see that this is a proposal from 14 1994? 15 A Yes. 16 Q This would have been within six months 17 of the CTFA Talc Interested Party Task Force -- 18 MR. DUFFY: Counsel, can you confirm 19 that what's in these exhibits is a composite 20 exhibit -- 21 MR. TISI: Absolutely. Absolutely. It 22 is two documents. The one is the actual 23 application itself. 24 MS. FRAZIER: Are there any other copies 25 of that since --</p>	<p>1 MR. TISI: Okay. I thought it was -- I 2 thought it was December 1994, but okay. 3 So -- and there's a -- there's actually 4 a letter sent to J&J listing this out, and I won't 5 go into detail about it. 6 BY MR. TISI: 7 Q But my question is this appears to be a 8 follow-up -- 9 MR. TISI: Do you have a copy of that 10 letter? 11 Okay. Could we take a break for one 12 minute while we get a copy of the letter? 13 THE VIDEOGRAPHER: The time is 2:06 p.m. 14 We're going off the record. 15 (Recess.) 16 THE VIDEOGRAPHER: The time is 2:16 p.m. 17 We're back on the record. 18 BY MR. TISI: 19 Q Doctor, I don't want to belabor the 20 point because I know we've been going a little 21 while, and I've got to turn my time over to other 22 people. 23 But do you know whether or not J&J -- 24 first of all, the study that you have in front of 25 you is a case controlled study.</p>
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<p>1 MR. TISI: Yeah. Yeah. 2 MR. DUFFY: This one kind of came apart. 3 MR. TISI: Okay. It was testified to by 4 Dr. Muscat the other day, so they refer to the 5 same thing. 6 The first -- and just to be clear for 7 the record, the top exhibit is a grant application 8 entitled "Talcum Powder Use in Ovarian Cancer, 9 Joshua Muscat, Research Scientist," on behalf of 10 the American Health Foundation. 11 There is actually a letter that goes 12 along with it as well, and attached is that actual 13 proposal for case controlled study of talcum 14 powder use and ovarian cancer. 15 MR. DUFFY: Thank you. 16 MR. TISI: You're welcome. 17 BY MR. TISI: 18 Q And I'll represent to you that both of 19 these documents are dated 2000 and -- actually, 20 1994. 21 A Okay. 22 MR. LOCKE: Well, one says, not the -- 23 January 31st, 1995. 24 MR. TISI: Okay. The second one? 25 MR. LOCKE: Yes.</p>	<p>1 A Okay. 2 Q Do you -- well, do you see it? It's 3 entitled "Proposal for a Case Controlled Study of 4 Talcum Powder Use in Ovarian Cancer." 5 MR. LOCKE: If you go back to page 78 at 6 the bottom there. 7 THE WITNESS: This one? Yep. Okay. I 8 see it, yes. 9 BY MR. TISI: 10 Q So there's a study -- this is actually a 11 study proposal, okay? 12 A Yes. 13 Q So just so we have the time frame down, 14 the -- in 1994, you all had a meeting. There was 15 a suggestion that J&J follow up and see whether or 16 not an additional study could be done by 17 Dr. Wynder's group. This is Dr. Wynder's group, 18 the American Health Foundation. They proposed a 19 study, and the study was a case controlled study. 20 Does that appear to be true? 21 MR. LOCKE: Objection. 22 THE WITNESS: That appears to be true. 23 BY MR. TISI: 24 Q Did -- now, the study, if you go back 25 one page, is about a \$400,000 study.</p>

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<p>1 A That's what it says, yes.</p> <p>2 Q All right. Now, I have a document</p> <p>3 here -- first of all, had you ever -- before</p> <p>4 coming here today, had you heard about this study</p> <p>5 or know anything about it?</p> <p>6 A I don't believe so, no.</p> <p>7 Q Okay. I'm going to provide you with a</p> <p>8 document, page -- it's Exhibit No. 15, and it says</p> <p>9 "Draft Never Sent," but I'm curious as to whether</p> <p>10 or not there was any other documents related to</p> <p>11 that.</p> <p>12 (Exhibit No. 64 was marked for</p> <p>13 identification.)</p> <p>14 MR. LOCKE: This is also marked 63.</p> <p>15 MR. TISI: Right -- oh, I'm sorry. Let</p> <p>16 me -- what number are we at now?</p> <p>17 MR. LOCKE: 64.</p> <p>18 MR. TISI: See without my -- so what's</p> <p>19 the next one we're at?</p> <p>20 MR. LOCKE: 64 is the one we're -- that</p> <p>21 one should -- would be.</p> <p>22 MR. TISI: Thank you, Tom.</p> <p>23 BY MR. TISI:</p> <p>24 Q Let me see if this somehow raises a --</p> <p>25 the specter to you that perhaps maybe this was</p>	<p>1 many possible confounders which had previously</p> <p>2 been ignored. The study will take two and a half</p> <p>3 years to complete and cost nearly \$400,000."</p> <p>4 Did I read that so far?</p> <p>5 A Yes.</p> <p>6 Q "We at J&J have reviewed the proposal</p> <p>7 and believe the study could help clarify the many</p> <p>8 obvious shortcomings in the previously reported</p> <p>9 studies. For as long as I've been on the Talc</p> <p>10 Interested Party Task Force, we have discussed</p> <p>11 ways to improve our understanding of cosmetic talc</p> <p>12 use. I think the task force should sponsor the</p> <p>13 study as an industry initiative. Would you please</p> <p>14 poll the members about the idea and put this</p> <p>15 subject on our upcoming task force meeting and</p> <p>16 agenda?"</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q And I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q Okay. Do you know whether or not J&J</p> <p>22 ever brought to the attention of the -- the CTFA</p> <p>23 the \$400,000 well-designed, carefully designed</p> <p>24 study that Dr. Muscat drafted when he was with the</p> <p>25 American Health Foundation?</p>
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<p>1 discussed with Dr. Gettings. First of all, this</p> <p>2 is --</p> <p>3 MR. GOLOMB: Could we just get that</p> <p>4 document up on the screen?</p> <p>5 MR. TISI: Yeah, May 5th -- it's 139.</p> <p>6 BY MR. TISI:</p> <p>7 Q And it says -- it's a -- it's a letter,</p> <p>8 and it says "Draft Never Sent" on top. So I don't</p> <p>9 want to -- I don't know whether you got it or you</p> <p>10 didn't get it or you got another version of it or</p> <p>11 whatever. I haven't seen anything in the records</p> <p>12 relating to this, but --</p> <p>13 A I haven't --</p> <p>14 Q -- I don't know whether or not anything</p> <p>15 in your -- in your travels you may have found</p> <p>16 something.</p> <p>17 It says, Dr. Gettings: "Dear Steve:</p> <p>18 This provides you with a copy of a talc proposal</p> <p>19 prepared by Dr. Joshua Muscat and Dr. Ernst Wynder</p> <p>20 of the American Health Foundation. They are</p> <p>21 proposing a new more definitive epidemiology study</p> <p>22 examining the hypothesized link between hygienic</p> <p>23 use of cosmetic talcum powder and the incidence of</p> <p>24 ovarian cancer. It is a very carefully designed</p> <p>25 study with special attention paid to -- paid to</p>	<p>1 MS. FRAZIER: Object to form.</p> <p>2 THE WITNESS: I'm not aware. I don't</p> <p>3 believe I've seen this or seen discussion of it.</p> <p>4 BY MR. TISI:</p> <p>5 Q Is this the kind of study that the -- I</p> <p>6 mean, we talked about the fact that the CTFA and</p> <p>7 PCPC was very interested in the science</p> <p>8 surrounding talc. Right?</p> <p>9 A Yes.</p> <p>10 Q And have been interested for decades,</p> <p>11 right?</p> <p>12 A Yes.</p> <p>13 Q Do you have any reason to believe that</p> <p>14 such a study had been brought to the attention of</p> <p>15 the CFTA that such a study would not have been</p> <p>16 funded and done?</p> <p>17 A I really don't know. I mean, I think</p> <p>18 you really would have to -- yeah, I can't say</p> <p>19 without having had that experience of bringing it</p> <p>20 and asking who was willing to do the funding.</p> <p>21 Q Has anybody -- has J&J ever proposed a</p> <p>22 study, in all of your experience with them, or</p> <p>23 proposed an action that CTFA decided it was not</p> <p>24 going to do, that you can think of?</p> <p>25 A We -- we -- I mean just overall, not</p>

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<p>1 outside of the area of talc, I mean sometimes we</p> <p>2 talk about studies and people either decide to do</p> <p>3 them or not.</p> <p>4 Q Okay. So -- but this study that was</p> <p>5 proposed by Dr. Muscat to help understand the</p> <p>6 issue was never sent to the members of the task</p> <p>7 force to the best of your knowledge?</p> <p>8 A I'm -- I'm not aware of it. I don't</p> <p>9 believe I've seen this before.</p> <p>10 Q Do you know why -- I mean in all this</p> <p>11 time, decades have gone by, and the -- the</p> <p>12 company -- the companies involved in the task</p> <p>13 force have never done an epidemiology study to</p> <p>14 study perineal talc and ovarian cancer?</p> <p>15 A I guess I can't answer that. I mean, I</p> <p>16 guess the question could be, you know, would it</p> <p>17 make a difference and would an industry study be</p> <p>18 taken without it being assumed that it wasn't as</p> <p>19 good as another study? I don't know. But I don't</p> <p>20 know.</p> <p>21 Q Okay. Well, that doesn't stop you all</p> <p>22 from doing studies, does it?</p> <p>23 A Well, it doesn't, except that it -- I</p> <p>24 mean it -- it becomes an issue.</p> <p>25 Q So you could always hire an outside</p>	<p>1 identification.)</p> <p>2 BY MR. TISI:</p> <p>3 Q This is a 2003 study. And I only have</p> <p>4 one copy, but since I know it by heart, I'm not</p> <p>5 going to need it.</p> <p>6 Do you know whether or not this is a</p> <p>7 study -- I assume you saw it. You're familiar</p> <p>8 with that study, it's a 2003 study by</p> <p>9 Dr. Huncharek?</p> <p>10 A I -- yes.</p> <p>11 Q Is that a study that -- were you aware</p> <p>12 of that study before it was published?</p> <p>13 A No.</p> <p>14 Q Okay. Was -- was PCPC in any way made</p> <p>15 aware of the study before it was published?</p> <p>16 A No.</p> <p>17 Q Okay. Did PCPC -- we discussed the two</p> <p>18 papers from Dr. Huncharek and Muscat that was in</p> <p>19 the letter from -- the e-mail from Mr. Glenn.</p> <p>20 A Yes.</p> <p>21 Q I can attach those two studies here.</p> <p>22 MR. TISI: Do you have those two</p> <p>23 studies?</p> <p>24 (Counsel conferring.)</p> <p>25 MR. TISI: 51 or 52, if you can get</p>
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<p>1 group to do it, right, and not have any role in</p> <p>2 the -- in the design of the study, no role in the</p> <p>3 editing of the study, no role -- no approve --</p> <p>4 approval or non-approval of the text, right? I</p> <p>5 mean there are times when that's done, right?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I guess I can't think of</p> <p>8 anywhere we've done a study like that.</p> <p>9 BY MR. TISI:</p> <p>10 Q Right. Because you always want to know</p> <p>11 what the authors are saying about a study you fund</p> <p>12 before you agree that it gets published, right?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, in general, yes,</p> <p>15 if we're funding a study, we want to --</p> <p>16 BY MR. TISI:</p> <p>17 Q So you're unaware of this particular</p> <p>18 study and why it was and was not done.</p> <p>19 A Yes. I don't believe I've seen it.</p> <p>20 Q Now, I'm going to show you a study that</p> <p>21 was done by Dr. Huncharek, Exhibit No. --</p> <p>22 MR. TISI: Which exhibit are we on?</p> <p>23 MR. LOCKE: 65.</p> <p>24 MR. TISI: Do you have a sticky?</p> <p>25 (Exhibit No. 65 was marked for</p>	<p>1 those.</p> <p>2 BY MR. TISI:</p> <p>3 Q Now, other than being aware of them</p> <p>4 before they were published, was PCPC involved in</p> <p>5 any way with the review of these articles?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: They were not.</p> <p>8 BY MR. TISI:</p> <p>9 Q Do you know who Brooke Mossman is?</p> <p>10 A I have heard the name. She's at</p> <p>11 Vermont, and I know it, yes.</p> <p>12 Q University at Vermont?</p> <p>13 A I think so.</p> <p>14 Q Do you know that she was involved in</p> <p>15 funded studies relating to the cellular response</p> <p>16 to -- to both asbestos and talc?</p> <p>17 A That sounds familiar, yes.</p> <p>18 Q Do you know that those studies were</p> <p>19 funded by IMA North America?</p> <p>20 A No. I mean, I -- I have probably run</p> <p>21 across that. I know they were not funded by us,</p> <p>22 but that --</p> <p>23 Q Okay. And that was my question is, do</p> <p>24 you know -- were you involved in any discussions</p> <p>25 about funding any studies by Dr. Mossman?</p>

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<p>1 A He may have been asked about it. I'm 2 not sure, but we did not fund any. 3 Q There was a study that Dr. Mossman 4 proposed. Are you familiar with the Shukla paper? 5 A Not by that name. 6 Q It's a Mossman -- it's a published 7 Mossman study. 8 A Okay. 9 Q Are you aware that Dr. Mossman had 10 proposed a follow-up study that industry declined 11 to fund? 12 A That sounds familiar. 13 Q Have you ever understood why a 14 company -- or what do you understand about that 15 study? 16 A I -- I am hard-pressed to remember what 17 it was about. 18 Q Do you understand that she wanted to 19 look at different kinds of talc and how it reacted 20 to ovarian cancer cells? 21 A I -- I just don't remember. 22 Q Do you know whether or not -- why PCPC 23 decided not to fund that study? 24 A If that's as I remember, because that's 25 how I remembered, is there was one study, and we</p>	<p>1 (Exhibit No. 66 was marked for 2 identification.) 3 BY MR. TISI: 4 Q First of all, if you go to page 10, it 5 says -- actually, hold on a second. 6 Okay. On page 12, it says: "Around 7 April 1997, CTFA sought the assistance of 8 consultant epidemiologists to evaluate a study on 9 powder exposure and perineal cancer." 10 A I'm sorry, page 12? 11 Q Page 12. 12 A Oh, second paragraph. Okay. 13 Q Do you see that? 14 A Yes. 15 Q Do you know what study that refers to? 16 A April '97. I should know. 17 Q The only study I found is the Cooke 18 study. Does that sound familiar? 19 A Oh, yeah. I think so. 20 Q Would that have been the Cooke study? 21 A I couldn't tell you off the top what 22 year the Cooke study was, but it would be -- 23 because I'm not thinking of any other event, I 24 think it would be a single study that -- 25 Q I'm going to show you the Cooke study,</p>
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<p>1 ask our people and -- if they want to fund, and 2 basically it's -- you know, either they do or they 3 don't, and we would not necessarily know, and nor 4 would -- nor would the reason be the same among 5 companies. 6 Q Did you ever discuss with either J&J or 7 Imerys why they were not interested in funding 8 that follow-up study by Dr. Mossman? 9 MS. FRAZIER: Object to form. 10 THE WITNESS: Not that I recall. 11 BY MR. TISI: 12 Q Now, let's go to -- I'd like to go to 13 the answers to interrogatories that were produced, 14 and I'm on my last page here. 15 Your counsel provided to us a set of -- 16 a second set of supplemental interrogatories on 17 Friday. 18 A Okay. 19 Q Have you seen them? 20 A I believe so, yes. 21 MR. LOCKE: Actually, I think it was 22 Thursday, but -- 23 MR. TISI: Okay. It doesn't matter to 24 me. I worked all weekend anyway. 25 MR. LOCKE: Okay. Thank you.</p>	<p>1 and it's Exhibit No. 67. 2 (Exhibit No. 67 was marked for 3 identification.) 4 BY MR. TISI: 5 Q And ask you whether you believe that 6 that's the case that you asked a consultant to 7 look at. 8 A So again, I think this was before I was 9 at CTFA, which is why I don't know. 10 Q Right. 11 A But I know we had a couple of individual 12 studies assessed, so timingwise, I guess this 13 makes sense. So I would -- 14 Q This is my only opportunity -- 15 A That seems plausible. 16 Q It's my only opportunity to really ask 17 questions of PCPC about this. 18 Do you believe that this is the study? 19 A I mean, if I -- if I saw that there was 20 a -- if we -- yes. I'm going to go yes. 21 Q Okay. 22 MR. LOCKE: Just for the record, we do 23 reference a document there that might shed light 24 on it in the interrogatory response. 25 MR. TISI: Yeah, and it's not -- it</p>

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<p>1 wasn't helpful, candidly, but I can go back and 2 figure it out. 3 BY MR. TISI: 4 Q It sought the assistance of consulting 5 epidemiologists to evaluate the article. Do you 6 know which epidemiologists they were? 7 A I don't. 8 Q Do you know whether it was Dr. Muscat? 9 A I don't think so. 10 Q Do you know that Dr. Muscat wrote a 11 letter to the editor regarding the Cooke paper? 12 A No, I don't -- I don't think I knew 13 that. I -- I wasn't aware -- again, I wasn't 14 here, so -- 15 Q I understand. I'm asking you with your 16 hat on as PCPC. 17 A No, totally agree. I just -- I'm just 18 saying I wasn't aware that we used Dr. Muscat 19 before 2000. 20 Q Okay. I'm going to show you -- I'm 21 going to put this -- and we will get an exhibit. 22 But here is a letter to the editor on 23 the -- 24 MR. TISI: Can you put it up? 25 (Counsel conferring.)</p>	<p>1 MR. LOCKE: We will see. Okay. 2 BY MR. TISI: 3 Q Okay. One last couple of questions, and 4 then I'm going to kind of be done with it. 5 I asked you whether or not the industry 6 or CTFA or individually the industry members had 7 done an epidemiology study studying ovarian cancer 8 and talc, and you had indicated that you were 9 unaware of any, correct? 10 A That's correct. 11 Q Are you aware of any study in which the 12 company did any toxicology studies on animals and 13 ovarian cancer? 14 A The -- through CTFA, the -- it was the 15 monkey study was -- I guess two monkey studies or 16 one -- one pre-study, one study on translocation. 17 Q Okay. But none looking at cellular -- 18 whether or not talc or any talc constituent causes 19 cellular changes in ovarian cancer cells in 20 animals? 21 A I can't think of anything. 22 Q Okay. And that would be something that 23 certainly could be done, right? 24 A I mean something -- 25 MR. LOCKE: Objection.</p>
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<p>1 BY MR. TISI: 2 Q I'm going to put it up on the screen and 3 we'll just have to substitute it. 4 And this will be Exhibit No. 68. 5 (Exhibit No. 68 was marked for 6 identification.) 7 BY MR. TISI: 8 Q And here is a letter to the editor in 9 1997 from Dr. Muscat and Dr. Wynder from the 10 American Health Foundation. 11 Do you see that on the screen? 12 A Sort of, yes. 13 Q I'm not going to ask you to comment on 14 it. 15 A Right. 16 Q I'm asking you do you believe that -- 17 that -- I'm trying to understand. 18 Would Dr. Muscat and the American Health 19 Foundation have been the epidemiologists with whom 20 you likely consulted to critique the Cooke paper? 21 A I guess I just would have to say that's 22 possible. 23 MR. TISI: Okay. Counsel, I'm going to 24 ask you, on behalf of PCPC, if you could clarify 25 that for us, if you don't mind.</p>	<p>1 THE WITNESS: Yeah, something could be 2 done, but you'd have to -- I mean, one would need 3 to think about that further as to what could be 4 done, if it would make sense. If it would, you 5 know, really shed any light on -- 6 BY MR. TISI: 7 Q Well, I mean, without being facetious, 8 you all had about 40 years to think about it. 9 The question is, did you ever talk with 10 amongst the members and say, Maybe we ought to do 11 an animal study seeing whether or not talcum 12 powder products or any constituent of those 13 products cause cellular changes in ovaries of any 14 particular animal? 15 MR. LOCKE: Objection. 16 THE WITNESS: I -- I'm not sure there 17 wasn't something done. Not by us, but -- no, we 18 didn't -- we didn't do anything. 19 BY MR. TISI: 20 Q Okay. Any -- there was a discussion in 21 one of the -- in the e-mail that Mr. Glenn sent 22 you in 2005 asking whether or not CTFA would do a 23 dose-response study, because that was one of the 24 Bradford Hill criteria that you all thought didn't 25 -- didn't support causation, and asked whether you</p>

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<p>1 would fund a study by Rothman or something that 2 could be published on dose-response. 3 Did you all discuss that? 4 MR. LOCKE: Objection. 5 THE WITNESS: We had Dr. Rothman's and 6 Dr. Samet's and Dr. Pastides' paper. 7 BY MR. TISI: 8 Q From 2000? 9 A His assessment. And we -- right, he -- 10 he did not propose reasonable terms that -- for us 11 to take that forward. 12 Q Okay. Could you explain that a little 13 more, because I'm not really sure -- 14 A He wanted to charge such an incredible 15 amount, it was far out of the ballpark of being 16 reasonable. 17 Q Okay. Well, I -- I'm still not 18 understanding. Did he propose to do a follow-up 19 study to look at dose-response? 20 A No. No, it wasn't -- it wasn't that. 21 He was proposing to turn his -- the submission 22 that he was -- coauthored into a publication. 23 Q Okay. And how much did he charge -- did 24 he want to charge? 25 A \$100,000.</p>	<p>1 Q That -- that report that was done by 2 Dr. Rothman and Pastides and Samet was never 3 submitted to a journal for peer review, was it? 4 MR. LOCKE: Just to clarify, you're 5 talking about the 2000 NTP? 6 MR. TISI: Correct. 7 THE WITNESS: Correct. It was submitted 8 to NTP. 9 BY MR. TISI: 10 Q But it was never submitted for 11 publication in any peer-reviewed journal. 12 A That's correct. 13 Q Okay. And you declined to support 14 that -- that submission for cost reasons, correct? 15 A Only because it was very unreasonable. 16 Q Okay. Did you ever propose to 17 anybody -- did anyone ever propose to PCPC or 18 anybody else that a dose-response study actually 19 be undertaken? 20 A I think that was talked about, and I 21 think there was concern that it was something that 22 had been done by somebody else, and should we be 23 doing that. And again, when I say the cost was 24 high, it was just well out of the bounds of what 25 you would expect. I mean it wasn't even close.</p>
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<p>1 Q And you all decided thanks but no 2 thanks? 3 A That's not a reasonable number. 4 Q Okay. And then in 2005, Luzenac came 5 back to you and said, you know, We really think 6 it's important to publish a study on dose- 7 response. Would you consider it? 8 And that was -- we could pull it out, 9 but that was the e-mail we talked about Huncharek 10 and Muscat. Do you remember that? 11 A Yes. 12 Q Did you go back to the well and say, you 13 know, Maybe you ought to publish it and do a 14 published study on dose-response? 15 MR. LOCKE: Objection. 16 THE WITNESS: No. Again, we had the 17 assessment done, but we -- no, we did not go 18 forward to have that made into a publication. 19 BY MR. TISI: 20 Q That publication was never subject to 21 peer review, was it? 22 A No. I mean it was -- it was a -- 23 Q I'm sorry. Let me rephrase the 24 question. 25 A Yeah.</p>	<p>1 Q Well, let me ask you this, and I will 2 represent to you -- and I don't have a copy of it 3 right here. Maybe I do. 4 This is Exhibit No. 69. 5 (Exhibit No. 69 was marked for 6 identification.) 7 BY MR. TISI: 8 Q I will represent to you in 2009, 9 Drs. Huncharek and Muscat proposed all kinds of 10 studies that could be done to further elucidate -- 11 elucidate the issue. Smoking and ovarian risks, 12 hysterectomy and tubal ligation, completion and 13 publication of Rothman's dose-response analysis, 14 et cetera, and then they subsequently propose 15 their own dose-response study. 16 Do you know whether any of those were 17 brought -- any of these proposals were brought to 18 the PCPC? 19 A I'm not aware that they were. 20 Q Okay. Do you currently have any studies 21 that you are -- have either considered -- well, 22 let me ask you this: Other than the ones we've 23 discussed, can you think of any study that was 24 proposed to the PCPC or by the PCPC relating to 25 the -- any issue relating to ovarian cancer and</p>

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<p>1 talc?</p> <p>2 A I'm sorry, what was the first part of</p> <p>3 your question?</p> <p>4 Q Do you know of any study that was either</p> <p>5 proposed to the PCPC or by the PCPC relating to</p> <p>6 any issue regarding talcum powder products and</p> <p>7 ovarian cancer?</p> <p>8 A I mean, I guess the monkey study, and</p> <p>9 then --</p> <p>10 Q No, that wasn't done. That was</p> <p>11 proposed.</p> <p>12 A Oh, that wasn't done.</p> <p>13 Q Yeah.</p> <p>14 A I think not a -- maybe not a hard core</p> <p>15 -- well, the ones you've talked about, I mean the</p> <p>16 Mossman. But again, I'm not sure there's any that</p> <p>17 came to proposal. I mean, I guess it's the things</p> <p>18 we're talking about now, right?</p> <p>19 Q Well, I'm asking if there's anything</p> <p>20 else.</p> <p>21 A Right.</p> <p>22 Q I mean, I'm trying to understand what</p> <p>23 you know. Right?</p> <p>24 So -- so are there -- I've tried to pull</p> <p>25 out some things that --</p>	<p>1 A We didn't do -- we didn't do one. I</p> <p>2 mean, there wasn't -- I guess it wasn't thought it</p> <p>3 would help or would be seen favorably coming from</p> <p>4 the industry or --</p> <p>5 Q Okay. Any studies relating to the</p> <p>6 purity of talc from potential carcinogens,</p> <p>7 including asbestos, did you ever sponsor --</p> <p>8 discuss any studies about that?</p> <p>9 A I mean, I think that goes back to when</p> <p>10 the specification was being put in place and all</p> <p>11 the testing was done, and then from then on, it</p> <p>12 was an ongoing work that was done by the industry,</p> <p>13 by the individual companies to --</p> <p>14 Q No, I -- you're thinking of something --</p> <p>15 I'm not talking about testing. I'm talking about</p> <p>16 any publications done to validate and study</p> <p>17 whether or not to test it was effective in</p> <p>18 removing potential carcinogens, including</p> <p>19 asbestos?</p> <p>20 A Any publication?</p> <p>21 Q Yeah.</p> <p>22 A I'm not --</p> <p>23 Q Or studies.</p> <p>24 A -- sure what you mean by publication.</p> <p>25 Q Or studies. Surveys, studies, anything</p>
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<p>1 A Right.</p> <p>2 Q -- I could see from the records.</p> <p>3 A Right.</p> <p>4 Q But I didn't live your life --</p> <p>5 A Right.</p> <p>6 Q -- so I don't know what -- what you</p> <p>7 know.</p> <p>8 A Yeah.</p> <p>9 Q So the question I'm asking you is, do</p> <p>10 you know whether or not, other than the studies</p> <p>11 we've talked about today, are there any other</p> <p>12 studies you can think that -- let's take them one</p> <p>13 at a time -- that were proposed to the PCPC to do</p> <p>14 that would investigate issues relating to ovarian</p> <p>15 cancer and talc?</p> <p>16 A I would say what I'm aware of is the</p> <p>17 group talked about kind of a brainstorming</p> <p>18 session. So not a proposal, not a fleshed-out</p> <p>19 proposal, but is there something we can do.</p> <p>20 Q And what kind of studies were -- were</p> <p>21 raised?</p> <p>22 A I mean, I think was there epidemiology</p> <p>23 work that we could do that -- that would help,</p> <p>24 kind of in a general sense.</p> <p>25 Q Okay. And the answer was?</p>	<p>1 like that.</p> <p>2 A I think that we relied on --</p> <p>3 Q The tests themselves.</p> <p>4 A Right, that the companies were carrying</p> <p>5 out ongoing.</p> <p>6 MR. TISI: All right. If you want to</p> <p>7 take a break, I think I'm done.</p> <p>8 THE VIDEOGRAPHER: The time is 2:44 p.m.</p> <p>9 We're going off the record.</p> <p>10 (Recess.)</p> <p>11 THE VIDEOGRAPHER: The time is 2:51 p.m.</p> <p>12 We're back on the record.</p> <p>13 CROSS-EXAMINATION</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Good afternoon, Doctor. I'm Richard</p> <p>16 Golomb. We met twice before.</p> <p>17 A Yes.</p> <p>18 Q I'm going to start where Mr. Tisi left</p> <p>19 off, and I'm going to try not to repeat -- repeat</p> <p>20 anything that he did, but I do want to clarify</p> <p>21 some things of where he left off.</p> <p>22 So the Rothman proposal was rejected, as</p> <p>23 you said, because of the cost of that study,</p> <p>24 correct?</p> <p>25 A I'm not sure really it was a proposal.</p>

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<p>1 I think we had gone to them, and they just made it 2 clear that it was going to be very, very expensive 3 if we wanted -- so we didn't carry it as far as to 4 a proposal. 5 Q Okay. You said in response to 6 Mr. Tisi's question that it was approximately 7 \$100,000. Where did you get that number if not 8 from a proposal? 9 A I -- I just -- just kind of a verbal. 10 Q From who? 11 A I think J&J actually went back and asked 12 him and -- and got a verbal on it. 13 Q When -- and when was that? 14 A It was after the NTP meeting. 15 Q Okay. And were you with -- with PCPC at 16 that time? 17 A Yes. 18 Q All right. So that was shortly after 19 you went onboard with PCPC? 20 A No, I started -- no, that was in 2000 -- 21 or probably 2000 -- I'm sure it was 2001. 22 Q Okay. 23 A I started PCPC in 1997. 24 Q All right. And the Wynder/Muscat 25 proposal, why was that rejected?</p>	<p>1 learn why it was that one or more of your members 2 rejected the Wynder/Muscat study? 3 A No. 4 Q All right. Now, in -- in addition to 5 Rothman and in addition to Wynder and in addition 6 to Muscat, there's a Dr. Wehner, correct, or 7 Wehner? 8 A Wehner, yes. 9 Q And that's spelled W-E-H-N-E-R? 10 A Correct. 11 Q All right. And the Wynder/Muscat 12 proposal was sometime in the early to mid-'90s, is 13 that your understanding? 14 A Whatever it was that I just saw. As I 15 say, we never -- we -- PCPC didn't see it, so I 16 would rather look at what it was than try to go by 17 memory. 18 Q Okay. Well, let me ask you this: You 19 have -- and I've asked you before about 20 Dr. Wehner, and you've reviewed some of the 21 documents from him as well, correct? 22 A Yes. 23 Q And those documents begin in the early 24 to mid-1990s, correct? 25 A Dr. Wehner did the study at Battelle, so</p>
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<p>1 A I -- I don't believe we ever saw that -- 2 PCPC ever saw that. 3 Q But at least one or more of your members 4 did? 5 A That's what it -- it looked like that 6 J&J saw it, yes. 7 Q And do you know why -- from your review 8 of the records, why that proposal was rejected? 9 A No. Again, I don't think we ever saw 10 it. 11 Q Okay. When you say "we," you say PCPC? 12 A Sorry, PCPC. I don't think PCPC ever 13 had that. 14 Q Okay. My question was a little bit 15 different. 16 While PCPC may not have seen the 17 proposal, one or more of your members did, and 18 rejected it, correct? 19 A As far as I know the study didn't 20 happen, so -- 21 Q Right. 22 A -- that would follow. 23 Q And my question was, based on your 24 review of the documents that assisted you in your 25 preparation for your deposition today, did you</p>	<p>1 that was in the early '80s. 2 Q Okay. Well -- 3 A Or mid-'80s. 4 Q -- he was -- 5 A Mid-'80s. 6 Q -- he was retained by the CFTA in the 7 early '90s, correct? 8 A In addition to doing that study, he was 9 retained in 2000, and he was retained at -- he -- 10 I know we paid for his travel to the IS RTP 11 workshop, so that would be the '94. 12 Q Okay. And you -- you recall in 13 preparation for your deposition last time, you 14 told me that you reviewed some of the letters from 15 Dr. Wehner, correct? 16 A Some of the letters? 17 Q Letters. 18 A I'm not sure what you mean my letters. 19 Q Okay. You don't know what I mean by a 20 letter? A letter, it was a piece of paper that 21 was -- that came from Dr. Wehner to somebody at 22 the CFTA, do you recall that? 23 A That was a proposal or -- 24 Q No, any letter. Do you recall any 25 letter from Dr. Wehner to the CFTA?</p>

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<p>1 A I mean, we hired him, so we had</p> <p>2 proposals, I guess. So, yes, documents.</p> <p>3 Q Did -- it's really -- it's not a trick</p> <p>4 question. I'm just trying to understand that</p> <p>5 you -- you in fact saw letters from Dr. Wehner to</p> <p>6 the CFTA outlining what it is that he was</p> <p>7 proposing that be done, correct?</p> <p>8 A I can think of at least one, yes.</p> <p>9 Q Okay. And included in those letters</p> <p>10 were also comments from Dr. Wehner about comments</p> <p>11 that the CFTA -- that Luzenac at that time, the</p> <p>12 predecessor of Imerys, some of the things that</p> <p>13 they were going to say publicly about the defense</p> <p>14 of talc and ovarian cancer, correct? Do you</p> <p>15 recall those?</p> <p>16 A I'm not sure what you mean. I'm --</p> <p>17 Q Okay. Do you recall in one of those</p> <p>18 letters that Dr. Wehner, in addition to</p> <p>19 Dr. Rothman, in addition to Dr. Wynder, in</p> <p>20 addition to Dr. Muscat, that Dr. Wehner also</p> <p>21 recommended that the CFTA and J&J and other</p> <p>22 members of the CFTA at that time also conduct</p> <p>23 their own study?</p> <p>24 A I'm not recalling specifically which</p> <p>25 document you're talking about.</p>	<p>1 case controlled study?</p> <p>2 A Maybe vaguely.</p> <p>3 Q Okay. And do you recall -- does it help</p> <p>4 refresh your recollection that in that letter</p> <p>5 dated in 1994, that in addition to recommending</p> <p>6 the study, Dr. Wehner put some parameters on it</p> <p>7 and said it would be easy to do and that you could</p> <p>8 get the results back within six months?</p> <p>9 A I think that sounds vaguely familiar,</p> <p>10 but I don't remember the details of what -- what</p> <p>11 he was proposing.</p> <p>12 Q And that study was never done, correct?</p> <p>13 A Again, I would really feel better seeing</p> <p>14 what it is, so that -- but a study by doctor -- a</p> <p>15 case controlled study by Dr. Wehner was never</p> <p>16 done, no.</p> <p>17 Q Right. And so -- and a case controlled</p> <p>18 study by Dr. Wynder or Dr. Muscat was never done,</p> <p>19 correct?</p> <p>20 A Again, PCPC was not even aware of that</p> <p>21 proposal.</p> <p>22 Q Okay. Isn't it true that none of these</p> <p>23 studies were done because PCPC and its members</p> <p>24 just didn't want to know the results?</p> <p>25 MR. LOCKE: Objection.</p>
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<p>1 Q Okay. Do you -- as you sit here today,</p> <p>2 do you recall that -- whether or not it was in a</p> <p>3 document or not, do you recall that Dr. Wehner</p> <p>4 made a recommendation to the CFTA to do its own</p> <p>5 study?</p> <p>6 A I'm not recalling that right now.</p> <p>7 Q And do you recall that in that letter</p> <p>8 back in 1994 that Dr. Wehner also told the CFTA</p> <p>9 that it would be easy to do and that the results</p> <p>10 would be -- would come back within six months? Do</p> <p>11 you recall that? Does that help refresh your</p> <p>12 recollection?</p> <p>13 A Can you -- can you show me the document,</p> <p>14 because I'm not sure what study you're talking</p> <p>15 about.</p> <p>16 Q Okay. Do --</p> <p>17 A Can you tell me what kind of study</p> <p>18 he's -- he's --</p> <p>19 Q Do you recall Dr. Wehner recommending</p> <p>20 any kind of study?</p> <p>21 A Well, I mean, he did a study for us, and</p> <p>22 he did various assessments of the data, but I</p> <p>23 think you're talking about something real</p> <p>24 specific, and I --</p> <p>25 Q Do you recall Dr. Wehner recommending a</p>	<p>1 THE WITNESS: No. I mean, we take the</p> <p>2 direction of our members, and the members' reasons</p> <p>3 for not funding would -- I mean, you would have to</p> <p>4 ask them.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Okay. So sitting here today, you don't</p> <p>7 know why it is that Rothman, Wynder, Muscat and</p> <p>8 Wehner were all rejected, their proposals. Is</p> <p>9 that what you're telling us?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: I think the only thing I</p> <p>12 could say would be the Rothman one, because that's</p> <p>13 one thing we looked at, and we knew that -- again,</p> <p>14 it's not all costs, but we were hoping for just a</p> <p>15 reasonable, normal cost, and that I think -- I'm</p> <p>16 sure we would have gone ahead, but it was in a</p> <p>17 ballpark that was just not rational.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Okay. And that ballpark was \$100,000?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: That -- that's my</p> <p>22 recollection, yes.</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q All right. And you are aware, are you</p> <p>25 not, that -- that before that decision was made,</p>

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<p>1 that Dr. Cramer had published on the association 2 between talc and ovarian cancer, correct? 3 A In 1982, yes. 4 Q Right. He also published in 1992. 5 A I know he published -- he was a coauthor 6 on the Gertig paper. 7 Q Right. And in that paper, in a footnote 8 in that paper he talks about the -- the numbers of 9 women who died from ovarian cancer. Do you recall 10 that? 11 A I do not. 12 Q All right. Tell me if this sounds 13 familiar: 22,000 women a year had ovarian cancer. 14 Does that sound familiar? 15 A That sounds like what I heard this 16 morning too. 17 Q Okay. And 14,000 women a year die from 18 ovarian cancer. Does that sound familiar? 19 A That sounds about a number I would 20 expect from the -- 21 Q Okay. And in Dr. Cramer's paper in 22 1992, he concludes that 10 percent of those women 23 die from a -- from talc and ovarian cancer. 24 MR. LOCKE: Object -- 25 BY MR. GOLOMB:</p>	<p>1 Citizen Petition. 2 Q Which one? 3 A The 2008, so the 2009 response. 4 Q So as far as you know, Dr. Huncharek did 5 not do any work for PCPC before 2008? 6 A I'm just trying to think and make sure 7 I'm not skipping anything. I think that's 8 correct. 9 Q Okay. And how was it that Dr. Huncharek 10 was retained by PCPC or one of its members? 11 A Again, it was -- 12 MR. LOCKE: Objection. 13 THE WITNESS: -- J&J that reached out to 14 him first. And they were familiar with him from 15 various work. 16 BY MR. GOLOMB: 17 Q Who was it at J&J? 18 A Who did I talk to at J&J at the time? I 19 don't remember. 20 Q Okay. So in the -- in the deposition 21 notice -- and I hate to tell you we're still on 22 topic 1, there's only 17 more to go -- but it 23 refers to the Weinberg Group. Do you know who the 24 Weinberg Group is? 25 A Yes.</p>
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<p>1 Q Do you recall that in the paper? 2 MR. LOCKE: Objection. Mischaracterizes 3 the paper. 4 BY MR. GOLOMB: 5 Q Do you recall that? 6 A I -- I recall something along those 7 lines. It doesn't mean we agreed with that, 8 though. 9 Q No, I understand. But that's -- that 10 is what was reported in 1992 before the decision 11 was made not to do a study that was recommended 12 by Dr. Rothman, Dr. Wynder, Dr. Muscat and 13 Dr. Wehner? 14 MR. LOCKE: Objection. 15 THE WITNESS: I mean, I -- if that's 16 what was said in the paper, again, I don't -- I 17 would have to look back, and we didn't agree with 18 that. 19 BY MR. GOLOMB: 20 Q All right. So let me ask you about 21 Dr. Huncharek, and I'm not going to go through the 22 study again. Mr. Tisi did that well. 23 When -- when did PCPC first retain 24 Dr. Huncharek for any reason? 25 A I believe it was for the answer to the</p>	<p>1 Q And who is the Weinberg Group? 2 A Weinberg Group is a consulting group, 3 and we hired them at the time of the NTP report to 4 pull together a binder, organize all the 5 information, and then reach out to consulting 6 epidemiologists. 7 Q All right. And that was in 1999, 2000? 8 A It was in 2000. 9 Q All right. And was -- did anybody from 10 the Weinberg Group talk to Dr. Huncharek at that 11 time, do you know? 12 A Not that I'm aware of. 13 Q Who did they talk to? 14 A The people that were hired through the 15 Weinberg Group were Drs. Rothman, Pastides, and 16 Samet, Dr. Samuel Shapiro, and Dr. Muscat. 17 Q All right. And they are -- some or all 18 of them were the ones who then wrote the report 19 that was then submitted to the NTP? 20 A There were three separate reports, and, 21 yes, those are the authors. Three of them on one 22 and then individuals from Muscat and Shapiro. 23 Q All right. And then somebody actually 24 made the report to the NTP, correct? 25 A Correct.</p>

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<p>1 MR. LOCKE: Objection. This material 2 was covered at length by Mr. Meadows. These 3 questions have been asked and answered. 4 MR. GOLOMB: I don't -- I'm not sure if 5 that's true or not, but I -- I don't -- I only 6 have a couple of minutes on this, so it's not 7 going to take much time. 8 THE WITNESS: Dr. Rothman made a 9 presentation on -- on that that there -- the 10 report that the three of them put together, the 11 review that the three of them put together. 12 BY MR. GOLOMB: 13 Q Okay. And it was -- you're saying -- 14 A So Dr. Pastides, not Dr. Rothman. 15 Q Okay. It was not Dr. Rothman, correct? 16 A That's correct, it was Dr. Pastides. 17 Q In fact, you recall in your review of 18 the documents that Dr. Rothman was kind of upset 19 that he wasn't able to make the presentation? Do 20 you recall that? 21 A Not really. 22 Q Okay. Burson-Marsteller, who is that? 23 A I think they're a -- I think they do 24 work for PCPC on our website or on our -- perhaps 25 on cosmeticsinfo.org. I think --</p>	<p>1 BY MR. GOLOMB: 2 Q Okay. That was an answer? 3 A Yeah, I think they work on our website. 4 I think they work on putting messages together, 5 and they work with our Public Affairs people. 6 Q Well, my question was who is 7 Burson-Marsteller? 8 A It's a company. 9 Q It's a company. All right. And is that 10 something you learned in your preparation for 11 today's deposition? 12 A I had heard of them, the name before. 13 Q All right. Who is Nichols-Dezenhall? 14 A Nichols-Dezenhall is a public affairs 15 company that did work for CTFA back some many 16 years ago. I'm not sure that we've used them at 17 all in recent years. They did a couple of focus 18 groups around the time of the NTP report on talc. 19 We use them I know for other things. 20 Q When did you learn about the focus 21 groups? 22 A In my preparation for this deposition. 23 Q Okay. Because you recall -- I was the 24 one who asked you about Nichols-Dezenhall before, 25 do you remember that?</p>
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<p>1 Q I'm sorry? 2 A Perhaps on cosmeticsinfo.org. 3 Q Who -- who are they? 4 A I think they're people that help prepare 5 information, and they work with our Public Affairs 6 department. 7 Q Okay. 8 A I think. 9 Q And so you're -- you're looking like you 10 don't know too much about them. 11 A I don't know too much about them. 12 Q All right. Did you -- you reviewed 13 the -- the notice of deposition before you 14 testified? 15 A Yes. 16 Q And so you know under 1(f), it 17 specifically says that we're going to ask 18 questions about Burson-Marsteller? 19 A Yes. 20 Q Okay. So did you prepare yourself to 21 answer questions about Burson-Marsteller? 22 MR. LOCKE: Why don't you ask her a 23 question about them. 24 MR. GOLOMB: Well, I did. 25 MR. LOCKE: And she answered.</p>	<p>1 MR. LOCKE: When you say "before," what 2 do you mean? 3 THE WITNESS: Yeah. 4 BY MR. GOLOMB: 5 Q In your prior deposition in July of 6 2018. 7 A I -- I couldn't recall who it was, but I 8 do remember being asked about that, and I gave an 9 answer that was not quite accurate, and that's why 10 I made sure I was clarified on that after the 11 fact. 12 Q All right. So did you review your -- 13 your deposition transcript from 2018 to help 14 prepare you today? 15 A I -- I read over it to see if there were 16 any things that I was confused about and made sure 17 I had answers -- my answers correct. 18 Q And I depose you in -- I think it was 19 2016 as well, correct? 20 A That's correct. 21 Q Did you review that in preparation for 22 your deposition today? 23 A Not today, no. 24 Q I also after your deposition in July of 25 2018 and before today depose Mr. Pollack. You</p>

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<p>1 know him, correct?</p> <p>2 A Yes.</p> <p>3 Q And just for the ladies and gentlemen of</p> <p>4 the jury, can you explain who Mr. Pollack is.</p> <p>5 A Mark Pollack is -- I should know his</p> <p>6 title, but he is an employee of the Personal Care</p> <p>7 Products Council. He reports directly to our CEO.</p> <p>8 He has an executive VP title. Perhaps it's for</p> <p>9 membership. I'm not sure.</p> <p>10 Q Okay. And did you read Mr. Pollack's</p> <p>11 deposition transcript?</p> <p>12 A I did not.</p> <p>13 Q All right. Can we go to document 50 --</p> <p>14 52415.</p> <p>15 This was a composite document. Which</p> <p>16 has been marked as Exhibit 70.</p> <p>17 (Exhibit No. 70 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q To me it appears to be a -- it's a PCPC</p> <p>21 document, and to me it appears to be a PowerPoint</p> <p>22 of some sort.</p> <p>23 Have you seen this before?</p> <p>24 A I may have seen it in my preparation.</p> <p>25 I'm not sure.</p>	<p>1 52418.</p> <p>2 Which is part of the same composite,</p> <p>3 correct?</p> <p>4 A Yes, so it appears.</p> <p>5 Q And it says: "Mission accomplished by</p> <p>6 promoting," and then the first bullet point says:</p> <p>7 "Voluntary industry self-regulation."</p> <p>8 Is that still a primary mission of PCPC?</p> <p>9 A I guess I would probably say no in the</p> <p>10 fact that we have been working on getting updated</p> <p>11 regulations passed for the cosmetic industry for</p> <p>12 the past 12 years.</p> <p>13 Q Well, let's go to the next document,</p> <p>14 which is PCPC 52424.</p> <p>15 And it says at the top "Self-regulation</p> <p>16 Programs," and under the first bullet point it</p> <p>17 says "CIR," correct?</p> <p>18 A Yes.</p> <p>19 Q All right. And CIR is still a</p> <p>20 self-regulatory program that is funded by the</p> <p>21 PCPC, correct?</p> <p>22 A It is still funded by the PCPC, correct.</p> <p>23 Q And it's still a self-regulatory</p> <p>24 program, correct?</p> <p>25 A I guess you could call it that. I mean,</p>
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<p>1 Q Okay. Can you tell us what it is?</p> <p>2 A Well, it looks like it's kind of an</p> <p>3 introduction to what is -- what is CTFA.</p> <p>4 Obviously, this is older since we're now PCPC.</p> <p>5 MR. LOCKE: And just for the record, I</p> <p>6 want to note it's missing quite a few pages, and</p> <p>7 some pages -- well --</p> <p>8 MR. TISI: Right. And for the record,</p> <p>9 it was about a 50-page document, and the ones I</p> <p>10 made copies of are the ones I'm asking questions</p> <p>11 about.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Is there anything, based on your review</p> <p>14 of those documents, that can tell us when this was</p> <p>15 used?</p> <p>16 A No. That's to say, only from CTFA that</p> <p>17 tells you something.</p> <p>18 Q Right. So when did CTFA change to PCPC?</p> <p>19 A Roughly 2006.</p> <p>20 Q Now, did you ever see this document</p> <p>21 before you were preparing for this deposition?</p> <p>22 A I doubt it.</p> <p>23 Q So do you know who prepared it?</p> <p>24 A No.</p> <p>25 Q Let's go to the next document, which is</p>	<p>1 we -- we undertook CIR because FDA didn't. So...</p> <p>2 Q The next document in that same</p> <p>3 PowerPoint is PCPC 52426.</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q And it basically is talking about the --</p> <p>7 the trade association obviously being at that time</p> <p>8 CTFA, now PCPC, and some of the -- the member</p> <p>9 services, correct?</p> <p>10 A Yes.</p> <p>11 Q And the first bullet point provides</p> <p>12 current information?</p> <p>13 A Yes.</p> <p>14 Q The second extends your resources,</p> <p>15 meaning that you can pull your resources like as</p> <p>16 in a task force.</p> <p>17 A That's one way, yes.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q And then the third bullet point is --</p> <p>21 allows you to influence industry policy and</p> <p>22 action. Correct?</p> <p>23 A Yes.</p> <p>24 Q And allows you to avoid direct</p> <p>25 company-government confrontation.</p>

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<p>1 A That's what it says.</p> <p>2 Q Right. So meaning that PCPC, or at that</p> <p>3 time CFTA, kind of acted as the intermediary to</p> <p>4 deal with the government confrontation?</p> <p>5 A For example, comments where the</p> <p>6 companies would -- where we would coordinate</p> <p>7 and -- and we would submit comments.</p> <p>8 Q Correct. Or as in this case, where</p> <p>9 the -- the CFTA would put its name on a document</p> <p>10 so that J -- J&J didn't have to.</p> <p>11 MR. LOCKE: Objection.</p> <p>12 THE WITNESS: We were -- we were the</p> <p>13 face of -- we were serving as the face of the</p> <p>14 industry.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Right. And in this case, though, you</p> <p>17 were serving as the face of the industry at the</p> <p>18 specific request of J&J, who said -- who basically</p> <p>19 concurred with the report that they reviewed, but</p> <p>20 suggested that it shouldn't be their name on it,</p> <p>21 it should be your name on it, correct?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: We had to agree with the</p> <p>24 report as well.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 clearance required.</p> <p>2 A There's no premarket approval, that's</p> <p>3 correct.</p> <p>4 Q As opposed to a pharmaceutical which</p> <p>5 does.</p> <p>6 A That the active ingredients would be</p> <p>7 approved, yes.</p> <p>8 Q Right. Cosmetics have less rigorous</p> <p>9 inspections --</p> <p>10 A Yes.</p> <p>11 Q -- than a pharmaceutical.</p> <p>12 And cosmetics have no specific standards</p> <p>13 for efficacy.</p> <p>14 A Well, cosmetics don't have efficacy the</p> <p>15 same way that drugs do, so that just kind of</p> <p>16 follows.</p> <p>17 Q Correct. That's part of the</p> <p>18 self-regulatory standard.</p> <p>19 A No, I mean, cosmetics are not -- they</p> <p>20 don't affect the structure or function of the</p> <p>21 body. That's by definition. So they don't have</p> <p>22 efficacy in a way that a drug would.</p> <p>23 Q Let's turn to 52505.</p> <p>24 Well, that's it, but it's upside down on</p> <p>25 the screen. There you go.</p>
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<p>1 Q All right. But that's to allow them to</p> <p>2 avoid direct company-government confrontation,</p> <p>3 correct?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I'm not sure that would be</p> <p>6 confrontation, but -- but, yes, we were the face</p> <p>7 of the industry.</p> <p>8 BY MR. GOLOMB:</p> <p>9 Q All right. And the next document is</p> <p>10 52457.</p> <p>11 This is essentially kind of describes</p> <p>12 the differences, does it not, between cosmetic and</p> <p>13 the pharmaceutical?</p> <p>14 A In some ways, yes. And I have to say</p> <p>15 this -- this is out of date. I mean, we would not</p> <p>16 produce something like this today.</p> <p>17 Q But it's still holds true, though. You</p> <p>18 may not produce it, but it still holds true.</p> <p>19 A Well, but -- no, what I'm saying is, for</p> <p>20 example, in this legislation that we are</p> <p>21 advocating for -- good manufacturing practices are</p> <p>22 a part of that, just as an example. So things</p> <p>23 change.</p> <p>24 Q But one -- one of the things that still</p> <p>25 holds true is that cosmetics have no prior FDA</p>	<p>1 So when this describes expert panels, it</p> <p>2 talks about liaison members, and I assume, correct</p> <p>3 me if I'm wrong, this is liaisoned from the -- at</p> <p>4 the time the CFTA to various governmental</p> <p>5 agencies, correct?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: I'm sorry. These are --</p> <p>8 yeah, there's three liaison members that still</p> <p>9 exist today. One is from FDA, one is from</p> <p>10 Consumer Federation of America, and one is</p> <p>11 representing industry.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Right. And these -- and so there was a</p> <p>14 lot of talk about John Bailey today.</p> <p>15 A Yes.</p> <p>16 Q So this is at a time when John Bailey</p> <p>17 was still at the FDA, correct?</p> <p>18 A Correct.</p> <p>19 Q And I want to understand the timeline of</p> <p>20 this. So with -- specifically with John Bailey.</p> <p>21 The -- the first Citizens Petition was</p> <p>22 in 1993, correct?</p> <p>23 A Yes.</p> <p>24 Q And that was at a time that John Bailey</p> <p>25 was at the FDA, correct?</p>

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<p>1 A Yes.</p> <p>2 Q And as -- as we saw from the letter,</p> <p>3 John Bailey at some point, representing the FDA,</p> <p>4 wrote a letter not rejecting the Citizens Petition</p> <p>5 but, rather, saying they didn't have the resources</p> <p>6 to deal with it at that time, correct?</p> <p>7 A I think that was just the initial</p> <p>8 response.</p> <p>9 Q The initial response in 1993, that's</p> <p>10 what I'm talking about.</p> <p>11 A Right, which is -- but that's -- I mean,</p> <p>12 that's how they respond to Citizens Petitions</p> <p>13 initially, I think almost always.</p> <p>14 Q I'm not -- I'm not questioning it one</p> <p>15 way or the other. I'm just trying to understand</p> <p>16 the timeline.</p> <p>17 A He wrote that initial letter in</p> <p>18 response, yes.</p> <p>19 Q Right. When he was -- when he was at</p> <p>20 the FDA.</p> <p>21 A At FDA, Yes.</p> <p>22 Q And then he gets hired by the CFTA when?</p> <p>23 A Okay. Let's see. I started in '97.</p> <p>24 It's like 2000 and -- let's see. He took my</p> <p>25 boss -- old boss's job in 2000 and --</p>	<p>1 A Correct.</p> <p>2 Q -- to the CFTA or the PCPC.</p> <p>3 A Correct.</p> <p>4 Q And that was after -- after he came to</p> <p>5 the PCPC, and Bailey set up the meeting with the</p> <p>6 FDA, correct?</p> <p>7 MR. LOCKE: Objection. Asked and</p> <p>8 answered.</p> <p>9 THE WITNESS: Right. When he came to</p> <p>10 the -- he eventually set up the meeting in 2009.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Right. And after he set up the meeting</p> <p>13 with his old subordinates, that's when the -- the</p> <p>14 Citizens Petition was rejected, correct?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 THE WITNESS: I think there were other</p> <p>17 things that went on in the meantime. For example,</p> <p>18 the assessment of the talcs -- admittedly not</p> <p>19 exhaustive, but the assessment of talcs for</p> <p>20 asbestos.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Well, but at that point in 2008, there</p> <p>23 had been 24 or more studies that already looked at</p> <p>24 the association between talc and ovarian cancer,</p> <p>25 and something like 18 of those studies showed a</p>
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<p>1 Q If you can speak up so that the --</p> <p>2 A I'm just ruminating instead of silence.</p> <p>3 Q Yeah, I know, but if you're going to</p> <p>4 ruminate out loud, you have to say it so the court</p> <p>5 reporter can get it.</p> <p>6 A Just trying to figure out -- it would</p> <p>7 have been roughly 2003, '2.</p> <p>8 Q Okay. And between 1993 and 2002 or</p> <p>9 2003, when Bailey came from the FDA to the CFTA,</p> <p>10 there had been no response to the Citizens</p> <p>11 Petition other than, We don't have the resources,</p> <p>12 correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I thought there was a</p> <p>15 response.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q And what was the response?</p> <p>18 A I thought the initial one was rejected.</p> <p>19 Q Okay. And is that something you saw</p> <p>20 today?</p> <p>21 A No, I haven't seen it today. We just</p> <p>22 saw the latter one today, the 2008, that was</p> <p>23 responded to in 2014.</p> <p>24 Q Right. And that was after Bailey had</p> <p>25 already come from the FDA --</p>	<p>1 statistically significant association between talc</p> <p>2 and ovarian cancer, correct?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: I would say there were --</p> <p>5 it's -- it's much more -- it's more complex than</p> <p>6 that. I mean, there were other issues, as have</p> <p>7 been pointed out, of biologic plausibility, of</p> <p>8 dose-response. So it's a little -- not as</p> <p>9 straightforward as that.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q Well, understood. I mean, we -- we -- I</p> <p>12 think we can agree that during this period of time</p> <p>13 between, you know, 1982 and 2008, that while there</p> <p>14 were all these other studies that were coming out,</p> <p>15 more than two dozen studies, most of which showed</p> <p>16 the statistically significant association, while</p> <p>17 at the same time Johnson & Johnson and the PCPC</p> <p>18 were rejecting case controlled studies of their</p> <p>19 own, but at that -- during that period of time,</p> <p>20 industry chose, rather than doing its own study,</p> <p>21 to do a critical analysis of the individual</p> <p>22 studies, correct?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: We did do critical</p> <p>25 analyses of the individual studies, yes.</p>

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<p>1 BY MR. GOLOMB:</p> <p>2 Q And -- but did not do its own study.</p> <p>3 A We did not do an epidemiology study.</p> <p>4 Q Mr. Tisi asked you before about the</p> <p>5 standard, and I've asked you about this before, so</p> <p>6 I'm not going to go into a lot of detail about it.</p> <p>7 But it's a document which was previously</p> <p>8 marked for identification as Plaintiff's Exhibit</p> <p>9 324 --</p> <p>10 MR. GOLOMB: Okay. That's fine.</p> <p>11 -- which we will mark as Exhibit 71.</p> <p>12 (Exhibit No. 71 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q All right. This is the Code of Federal</p> <p>16 Regulations, Title 21. Are you familiar with</p> <p>17 this?</p> <p>18 A Yes.</p> <p>19 Q Were you aware of this before I asked</p> <p>20 you about it?</p> <p>21 A I -- I'm not familiar with specifically</p> <p>22 these labeling requirements, and we don't get into</p> <p>23 issues of labeling beyond telling our -- helping</p> <p>24 our companies understand what current labeling</p> <p>25 requirements are in our labeling manual.</p>	<p>1 THE WITNESS: Yeah, we don't -- PCPC</p> <p>2 does not get into labeling.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Right. And as far as you know, the FDA</p> <p>5 also doesn't tell a company what to put on a</p> <p>6 label, correct?</p> <p>7 MR. LOCKE: Objection. Beyond the</p> <p>8 scope.</p> <p>9 THE WITNESS: I mean, the FDA opined on</p> <p>10 the Citizens Petitions.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Well, but they don't tell the company</p> <p>13 when -- when to put a label on and when not to,</p> <p>14 correct?</p> <p>15 MR. LOCKE: Objection. Beyond the</p> <p>16 scope.</p> <p>17 THE WITNESS: I really don't know.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q All right. Did you at any time in</p> <p>20 preparation for any of these depositions read the</p> <p>21 testimony of Dr. Bailey?</p> <p>22 A I did not.</p> <p>23 Q Okay. Were you aware that Dr. Bailey</p> <p>24 has testified not in a -- in an ovarian cancer</p> <p>25 case, but in an asbestos case where he discussed</p>
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<p>1 Q Okay. But I -- I've asked you about</p> <p>2 this before, correct? Do you recall that?</p> <p>3 A I -- I -- I don't recall specifically.</p> <p>4 Q All right. This is the Code of Federal</p> <p>5 Regulations, Title 21, Section 740.1,</p> <p>6 "Establishment of Warning Statements."</p> <p>7 Did I read that correctly?</p> <p>8 A Yes.</p> <p>9 Q And can you just read subsection (a) for</p> <p>10 the jury, please.</p> <p>11 A "The label of a cosmetic product shall</p> <p>12 bear a warning statement whenever necessary or</p> <p>13 appropriate to prevent a health hazard that may be</p> <p>14 associated with the product."</p> <p>15 Q "That may be associated with the</p> <p>16 product," correct?</p> <p>17 A That's what it says.</p> <p>18 Q All right. And that is a determination</p> <p>19 of whether or not a company is going to label a</p> <p>20 cosmetic product with a warning statement. That</p> <p>21 is a decision to be made by the company, correct?</p> <p>22 A That's --</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: That's not something --</p> <p>25 MR. LOCKE: Beyond the scope.</p>	<p>1 very specifically the role of the FDA in</p> <p>2 cosmetics?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: I mean, I knew he</p> <p>6 testified. I don't know any specifics beyond</p> <p>7 that.</p> <p>8 BY MR. GOLOMB:</p> <p>9 Q All right. I want to move to topic 7,</p> <p>10 which is the National Cancer Institute.</p> <p>11 What is the National Cancer Institute?</p> <p>12 A It's a governmental agency. I'm not</p> <p>13 sure "agency" is the right word. It's a</p> <p>14 governmental body that I believe funds cancer</p> <p>15 research.</p> <p>16 Q And what -- what, if any,</p> <p>17 communications, directly or indirectly, does the</p> <p>18 PCPC have with the NCI generally?</p> <p>19 A I'm not aware of any.</p> <p>20 Q At any time?</p> <p>21 A I'm not aware of any, no, at any time.</p> <p>22 Q All right. Have you ever -- and I'm</p> <p>23 not -- when I say "you," I'm talking about anybody</p> <p>24 at PCPC because that's your role here today --</p> <p>25 A Yes.</p>

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<p>1 Q -- to testify on behalf of PCPC.</p> <p>2 Have you had any contact with a member</p> <p>3 organization, be it J&J, Luzenac, Rio Tinto,</p> <p>4 Imerys, or any other member, where you have</p> <p>5 learned that they've had contact with the NCI?</p> <p>6 A Not that I'm aware of.</p> <p>7 Q So when the NCI on a number of occasions</p> <p>8 on their website identifies talc as a risk of</p> <p>9 ovarian cancer, and then that was taken off the</p> <p>10 website, you have no idea why?</p> <p>11 A Correct.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 BY MR. GOLOMB:</p> <p>14 Q Okay. Were you -- were you aware of</p> <p>15 that before I just told you that?</p> <p>16 A I was, and I can't remember how I became</p> <p>17 aware of that. I'm not sure I was ever aware that</p> <p>18 it was on. I was maybe aware that it was off.</p> <p>19 But I -- I don't recall --</p> <p>20 Q Have you ever --</p> <p>21 A -- when I learned that.</p> <p>22 Q I'm sorry. I didn't mean to interrupt.</p> <p>23 A Oh, no, since I don't -- I'm not aware</p> <p>24 of when I learned that. I mean, I just can't</p> <p>25 remember.</p>	<p>1 A I wouldn't have because I am absolutely</p> <p>2 certain they would not do that without talking to</p> <p>3 the Science department.</p> <p>4 Q And why do you say that?</p> <p>5 A Because that's just the way we work. I</p> <p>6 mean, when -- when the Public Affairs, for</p> <p>7 example, is doing any kind of a science issue,</p> <p>8 they're consulting with us. They're not doing</p> <p>9 that on their own.</p> <p>10 Q Let's go to the next document, which</p> <p>11 we'll mark as Exhibit 72.</p> <p>12 (Exhibit No. 72 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q And this again is --</p> <p>16 (Counsel conferring.)</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Yeah, it's been previously marked for</p> <p>19 identification as P-72. It's up on the screen.</p> <p>20 (Counsel conferring.)</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Now, this was the NCI website as of</p> <p>23 September 15th, 2011. You can see that from the</p> <p>24 lower right-hand corner. Do you see that?</p> <p>25 A Yes.</p>
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<p>1 Q Okay. Have you ever looked at the NCI</p> <p>2 website for any reason?</p> <p>3 A I think I looked at that having heard</p> <p>4 about that.</p> <p>5 Q Well, you have a -- my word, not</p> <p>6 yours -- I know we have previously gone through</p> <p>7 the organizational chart in great detail, and</p> <p>8 there was a Public Relations/Communications</p> <p>9 department, correct?</p> <p>10 A On -- on our website?</p> <p>11 Q On PCPC.</p> <p>12 A We have -- yes.</p> <p>13 Q Right. And in preparation for this</p> <p>14 deposition, you were asked very specifically about</p> <p>15 communications, directly or indirectly, with the</p> <p>16 NCI concerning the risk of ovarian cancer caused</p> <p>17 by application of talcum powder.</p> <p>18 A Okay. Yes.</p> <p>19 Q And so in your role as a 30(b)(6)</p> <p>20 witness, did you go to any of the employees within</p> <p>21 the Communications department, Public Relations</p> <p>22 department, whatever you call it, as well as</p> <p>23 the -- the -- and again my word, not yours -- the</p> <p>24 lobbying arm of PCPC to find out if they had any</p> <p>25 communications with the NCI?</p>	<p>1 Q And this is the "Ovarian Cancer</p> <p>2 Prevention, PDQ, Prevention Patient Information."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Now, are you familiar with the PDQ?</p> <p>6 A Um --</p> <p>7 Q Not this one in particular. A PDQ</p> <p>8 generally.</p> <p>9 A I'm trying to -- I'm not sure I know</p> <p>10 what it stands for. I think, again, because I've</p> <p>11 seen something along these lines, I --</p> <p>12 Q It's a Physician's Data Query.</p> <p>13 A Okay.</p> <p>14 Q Does that sound familiar?</p> <p>15 A Yeah, it does now. Yeah.</p> <p>16 Q Okay. And so in order to go on to the</p> <p>17 website and go specifically to the PDQ, you have</p> <p>18 to be a physician or scientist that has access.</p> <p>19 Is that consistent with your understanding?</p> <p>20 MR. LOCKE: Objection. Beyond the</p> <p>21 scope.</p> <p>22 THE WITNESS: Yeah, I just wouldn't have</p> <p>23 known that.</p> <p>24 BY MR. GOLOMB:</p> <p>25 Q Okay. And that's fine, by the way. If</p>

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<p>1 you don't know, it's --</p> <p>2 A Right. I don't know.</p> <p>3 Q So that if a -- a woman who has ovarian</p> <p>4 cancer and is claiming that she got her ovarian</p> <p>5 cancer from the use of talcum powder, she would</p> <p>6 not, unless she was a physician or a scientist,</p> <p>7 have access to the PDQ. Is that consistent with</p> <p>8 your understanding?</p> <p>9 MR. LOCKE: Objection. Beyond the</p> <p>10 scope.</p> <p>11 THE WITNESS: I think only just from</p> <p>12 what you just said, that access is limited to</p> <p>13 physicians, so...</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Okay. Well, on the other hand, if</p> <p>16 anybody went on to the NCI website, and in the</p> <p>17 search box typed in "ovarian cancer," they would</p> <p>18 get a -- a Snapshot of Ovarian Cancer. Is that</p> <p>19 consistent with your understanding?</p> <p>20 MR. LOCKE: Objection. Beyond the</p> <p>21 scope.</p> <p>22 THE WITNESS: I guess. Again, I'm not</p> <p>23 sure.</p> <p>24 BY MR. GOLOMB:</p> <p>25 Q Okay. So if you take a look at</p>	<p>1 the NCI as of September 5th, 2011, correct?</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 THE WITNESS: September 15th, but yes.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q 2011.</p> <p>7 A That's -- that's the date of this</p> <p>8 document, yes.</p> <p>9 Q Okay. Now, let's go to the next</p> <p>10 document, which is MBS-CRE271.</p> <p>11 (Exhibit No. 73 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. GOLOMB:</p> <p>14 Q Have you seen that before?</p> <p>15 A I saw it in preparation for this.</p> <p>16 Q Okay. Do you need time to review it now</p> <p>17 or --</p> <p>18 A Yes.</p> <p>19 Q -- or are you familiar with it?</p> <p>20 A No, I need time to review it.</p> <p>21 Q Go ahead.</p> <p>22 A (Peruses document.) Okay.</p> <p>23 Q This is an e-mail exchange back in April</p> <p>24 of 2013 between William Kelly, Jr., and Jim Tozzi,</p> <p>25 correct?</p>
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<p>1 Exhibit -- what was it 72? -- if you take a look</p> <p>2 at Exhibit 72 --</p> <p>3 A Okay.</p> <p>4 Q -- this is the PDQ on ovarian cancer</p> <p>5 prevention, correct?</p> <p>6 MR. LOCKE: Just to be clear, it's</p> <p>7 pages 1 and 3 of a seven-page document.</p> <p>8 MR. GOLOMB: Correct. And that was to</p> <p>9 show the cover page and the portions relevant to</p> <p>10 talc.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q So if you go to page 3 of that document,</p> <p>13 in the middle of the document it refers to talc.</p> <p>14 Do you see that?</p> <p>15 A I do see that.</p> <p>16 Q And it says: "The use of talc may</p> <p>17 increase the risk of ovarian cancer. Talcum</p> <p>18 powder dusted on the perineum, the area between</p> <p>19 the vagina and the anus, may reach the ovaries by</p> <p>20 entering the vagina."</p> <p>21 Do you see that?</p> <p>22 A That's what it says, yes.</p> <p>23 Q Did I read that correctly?</p> <p>24 A Yes.</p> <p>25 Q So that was a -- posted on the PDQ of</p>	<p>1 A Correct.</p> <p>2 Q Who is William Kelly, Jr.?</p> <p>3 A He is with the CRE.</p> <p>4 Q And who is Jim Tozzi?</p> <p>5 A Also with CRE, I believe.</p> <p>6 Q And if you look at the middle e-mail on</p> <p>7 page 1 of 2, from Jim Tozzi to Bill Kelly,</p> <p>8 April 15th, 2013, at 11:12 a.m. Do you see that?</p> <p>9 A Yes.</p> <p>10 Q It says -- the second -- the last line</p> <p>11 on that e-mail says: "Showing that the CIR as</p> <p>12 unbiased and cleaning up material on the internet</p> <p>13 is critical if they are going to calm down</p> <p>14 lawsuits."</p> <p>15 A That's what it says.</p> <p>16 Q Do you know what he's referring to when</p> <p>17 he says "cleaning up material on the internet"?</p> <p>18 MR. LOCKE: Objection. Beyond the</p> <p>19 scope.</p> <p>20 THE WITNESS: I don't. We didn't see</p> <p>21 this. We never talked to them about this.</p> <p>22 BY MR. GOLOMB:</p> <p>23 Q And do you know what he means by "calm</p> <p>24 down lawsuits"?</p> <p>25 MR. LOCKE: Same objection.</p>

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<p>1 THE WITNESS: I mean, obviously he is</p> <p>2 referring to litigation, I presume. But --</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Okay. Well, are you aware one way or</p> <p>5 the other as to whether or not there was any</p> <p>6 litigation in which any of these companies were</p> <p>7 sued as a result of the -- the relationship</p> <p>8 between talc and ovarian cancer as of April 13 --</p> <p>9 April 15th, 2013?</p> <p>10 MR. LOCKE: When you say "any of these</p> <p>11 companies," to whom are you referring?</p> <p>12 MR. GOLOMB: J&J and Imerys and their</p> <p>13 predecessors.</p> <p>14 MR. LOCKE: Objection. Beyond the</p> <p>15 scope.</p> <p>16 THE WITNESS: Yeah, I don't know the</p> <p>17 dates of lawsuits, and I -- I just don't know.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Okay. The -- on the bottom of the page,</p> <p>20 there's an e-mail from William Kelly, Jr., to</p> <p>21 Tozzi on April 15th, 2013, just 24 minutes before,</p> <p>22 at 12:48 p.m.</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q And if we look at the second paragraph</p>	<p>1 assume because it's an unusual name, that's who he</p> <p>2 is talking about, yes.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q All right. And do you know -- do you</p> <p>5 know Mr. Sharma?</p> <p>6 A I may have been on a phone call with him</p> <p>7 once or twice, but I don't know if I've met him.</p> <p>8 Q All right. Have you ever spoken to him</p> <p>9 specifically about talc and its association with</p> <p>10 ovarian cancer?</p> <p>11 A As I said, I may have been on a phone</p> <p>12 call, and I can't remember context, but -- I mean,</p> <p>13 it'd be on a conference call. I don't believe</p> <p>14 I've ever spoken to him one on one.</p> <p>15 Q All right. And if we look at the last</p> <p>16 sentence going on to the next, the first sentence</p> <p>17 of the next page, it says: "Shripal knows that we</p> <p>18 engineered the CIR report from the outset."</p> <p>19 Did I read that correctly?</p> <p>20 A That's what it says.</p> <p>21 Q And that's from one CRE employee to</p> <p>22 another?</p> <p>23 A That's what it looks like.</p> <p>24 Q Let -- let's take a look at the next</p> <p>25 document, which was previously marked for</p>
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<p>1 that begins: "The only account I am working on</p> <p>2 currently is talc." Do you see that?</p> <p>3 A Yes.</p> <p>4 Q And that is -- that's William Kelly, Jr.</p> <p>5 saying that, correct?</p> <p>6 A Yes.</p> <p>7 Q And in the -- it says: "The only</p> <p>8 account I am working on currently is talc. Of</p> <p>9 course, I also want to write an article on the IQA</p> <p>10 during the next six months as well as clean up the</p> <p>11 Wikipedia entry on the IQA."</p> <p>12 What is the IQA?</p> <p>13 A I have --</p> <p>14 MR. LOCKE: Objection. Beyond the</p> <p>15 scope.</p> <p>16 THE WITNESS: I don't know.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q And then it refers to somebody named</p> <p>19 Shripal. Do you see that?</p> <p>20 A Yeah -- yes.</p> <p>21 Q Who is that?</p> <p>22 A Shripal is somebody at Imerys.</p> <p>23 Q Right, that's Shripal Sharma, correct?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 THE WITNESS: I -- I mean, I would</p>	<p>1 identification as Plaintiff's Exhibit P-225.</p> <p>2 (Exhibit No. 74 was marked for</p> <p>3 identification.)</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q This is another Ovarian Cancer</p> <p>6 Prevention PDQ, correct?</p> <p>7 A Yes.</p> <p>8 Q And you'll see on the bottom right-hand</p> <p>9 corner it's dated June 12, 2013.</p> <p>10 A Yes.</p> <p>11 Q Approximately two years after the last</p> <p>12 one I showed you.</p> <p>13 A Approximately.</p> <p>14 Q And if you go on to the next page,</p> <p>15 towards the bottom quarter of the page, it refers</p> <p>16 to talc, correct?</p> <p>17 A I only have page 1.</p> <p>18 Q I'm going to hand you my copy and ask</p> <p>19 you to turn to page 2.</p> <p>20 Do you see the highlighted area?</p> <p>21 A Yes.</p> <p>22 Q Can you just read that for the jury,</p> <p>23 please.</p> <p>24 A It says, quote: "The use of talc may</p> <p>25 increase the risk of ovarian cancer. Talcum</p>

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<p>1 powder dusted on the perineum, the area between</p> <p>2 the vagina and the anus, may reach the ovaries by</p> <p>3 entering the vagina."</p> <p>4 Q Okay. And that was in June of 2013,</p> <p>5 after the first of the lawsuits in the -- in these</p> <p>6 cases were filed. Are you aware of that?</p> <p>7 MR. LOCKE: Objection. Beyond the</p> <p>8 scope.</p> <p>9 THE WITNESS: I'm not aware of the</p> <p>10 dates, no.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Okay. Let me show you the next</p> <p>13 document, which has been marked as P-384.</p> <p>14 (Exhibit No. 75 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q This is another Ovarian Cancer</p> <p>18 Prevention PDQ, correct?</p> <p>19 A Yes.</p> <p>20 Q All right. And this is a little bit</p> <p>21 different format taken from the website than</p> <p>22 previous ones, correct?</p> <p>23 A Yes.</p> <p>24 Q And do you see the -- the date of this</p> <p>25 in the bottom of the page?</p>	<p>1 the vagina and the anus, may reach the ovaries by</p> <p>2 entering the vagina."</p> <p>3 Q Okay. Thank you.</p> <p>4 Let me show you the next document.</p> <p>5 And this is a document which has been</p> <p>6 previously marked for identification as P-385.</p> <p>7 (Exhibit No. 76 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. GOLOMB:</p> <p>10 Q Have you seen this document before?</p> <p>11 A Not that I know of, no.</p> <p>12 Q All right. Now, you'll see at the</p> <p>13 bottom this document was dated March 19th, 2015.</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And this is after the IARC report that</p> <p>17 came out and declared talc a Class 2B carcinogen,</p> <p>18 correct?</p> <p>19 MS. FRAZIER: Object to form.</p> <p>20 MR. LOCKE: Objection. I'm not going to</p> <p>21 direct the witness not to answer, but she's</p> <p>22 testified she has not seen these exhibits</p> <p>23 previously. I'm -- there's a lack of foundation.</p> <p>24 It's beyond the scope.</p> <p>25 You can answer to the extent you can.</p>
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<p>1 A It's hard to read, but it's, I think,</p> <p>2 August 18, 2014.</p> <p>3 Q And at the top of the page, it says:</p> <p>4 "The following risk factors may increase the risk</p> <p>5 of ovarian cancer." Do you see that?</p> <p>6 A I do.</p> <p>7 Q And the -- the fifth risk factor there</p> <p>8 is what?</p> <p>9 A It says --</p> <p>10 MR. LOCKE: Objection. Beyond the</p> <p>11 scope.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Is what?</p> <p>14 A It says "talc."</p> <p>15 Q And from the same document, page 2 of 3,</p> <p>16 it specifically refers to talc, correct?</p> <p>17 MR. LOCKE: Objection. Beyond the</p> <p>18 scope.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. GOLOMB:</p> <p>21 Q And can you just read that for the jury,</p> <p>22 please.</p> <p>23 A It says, quote: "The use of talc may</p> <p>24 increase the risk of ovarian cancer. Talcum</p> <p>25 powder dusted on the perineum, the area between</p>	<p>1 THE WITNESS: And so what was the</p> <p>2 question?</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q This document is dated March 19th,</p> <p>5 2015 --</p> <p>6 A Correct.</p> <p>7 Q -- which is after the IARC report came</p> <p>8 out, correct?</p> <p>9 A Yes.</p> <p>10 Q The IARC report which announced that</p> <p>11 the -- they concluded that talc was a Class 2B</p> <p>12 carcinogen, correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: Based on limited evidence.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q And in fact, this Ovarian Cancer</p> <p>17 Prevention PDQ that we're now referring to refers</p> <p>18 to the IARC report, correct?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q And do you see at the bottom third of</p> <p>23 the page, it says "Perineal Talc Exposure"?</p> <p>24 A Yes.</p> <p>25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 692</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Can you just read that for us, please.</p> <p>3 A It says, quote: "Based on solid</p> <p>4 evidence, perineal application of talc is</p> <p>5 associated with a small increased risk of ovarian</p> <p>6 cancer. The International Agency for Research on</p> <p>7 Cancer has concluded that perineal talc is a</p> <p>8 possible carcinogen."</p> <p>9 Q And then it talks about the magnitude of</p> <p>10 the effects, correct?</p> <p>11 A It does.</p> <p>12 Q And it says an odds ratio of 1.24,</p> <p>13 correct?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: That's what it says.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q Meaning that there is nearly a 25</p> <p>18 percent increased risk of harm, correct?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 THE WITNESS: Well, there's a confidence</p> <p>21 interval with that, but that's a -- that's what</p> <p>22 the odds ratio is.</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q Right. And do you have enough</p> <p>25 experience in epidemiology to understand that that</p>	<p style="text-align: right;">Page 694</p> <p>1 BY MR. GOLOMB:</p> <p>2 Q Now, just to refresh your recollection</p> <p>3 before you -- and I'll give you whatever time you</p> <p>4 need -- when we were talking before about the PDQ,</p> <p>5 I also referred to the snapshot. Do you recall</p> <p>6 that?</p> <p>7 A Yes.</p> <p>8 Q And so this is a Snapshot of Ovarian</p> <p>9 Cancer from the NCI website. Do you understand</p> <p>10 that?</p> <p>11 MR. LOCKE: Objection. Beyond the</p> <p>12 scope, lack of foundation, form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q And that's dated August 8th, 2016,</p> <p>16 correct?</p> <p>17 MR. LOCKE: Same objections.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Have you -- have you seen this document</p> <p>21 before?</p> <p>22 A Again, I -- well, I think I've seen</p> <p>23 something from NCI once upon a time. It would</p> <p>24 be -- I don't know what the date would be, so my</p> <p>25 answer's going to be no.</p>
<p style="text-align: right;">Page 693</p> <p>1 is statistically significant?</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 THE WITNESS: I think it depends --</p> <p>5 MR. LOCKE: Calls for expert testimony.</p> <p>6 THE WITNESS: Yeah, it depends on what</p> <p>7 study you're looking at. And I -- I'm surprised</p> <p>8 that they say "based on solid evidence," because</p> <p>9 that was -- this finding was specifically based on</p> <p>10 limited evidence was the conclusion.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Well, the National Cancer Institute</p> <p>13 wrote "based on solid evidence," correct?</p> <p>14 A Yes.</p> <p>15 Q And you've never seen this before,</p> <p>16 correct?</p> <p>17 A Yes.</p> <p>18 Q So you don't know what the National</p> <p>19 Cancer Institute is basing their -- their</p> <p>20 conclusion that it's based on solid evidence?</p> <p>21 A Yeah. Actually, you're right. I was</p> <p>22 looking at the IARC sentence.</p> <p>23 Q Okay. Let's go to P-437.</p> <p>24 (Exhibit No. 77 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 695</p> <p>1 Q Okay. And --</p> <p>2 MR. LOCKE: I also want to note this is</p> <p>3 just one of six pages.</p> <p>4 MR. GOLOMB: Right. And this is the</p> <p>5 page that refers to talc.</p> <p>6 BY MR. GOLOMB:</p> <p>7 Q Do you see in the lower half portion of</p> <p>8 that page, the Snapshot of Ovarian Cancer, under</p> <p>9 Incidence and Mortality, it has risk factors for</p> <p>10 ovarian cancer. Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And if you go down to the fourth line,</p> <p>13 do you see it says there "The use of talc"?</p> <p>14 A Yes.</p> <p>15 Q So as of August 8, 2016, on the Snapshot</p> <p>16 of Ovarian Cancer, the NCI website tells people</p> <p>17 that the use of talc is a risk factor, correct?</p> <p>18 MS. FRAZIER: Objection to form.</p> <p>19 MR. LOCKE: Objection.</p> <p>20 BY MR. GOLOMB:</p> <p>21 Q For ovarian cancer.</p> <p>22 MR. LOCKE: Lack of scope -- or beyond</p> <p>23 the scope, lack of foundation, form.</p> <p>24 THE WITNESS: This says risk factor for</p> <p>25 ovarian cancer, and it includes in their list use</p>

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<p>1 of talc.</p> <p>2 MR. GOLOMB: Okay. Can we go to the</p> <p>3 next document, please.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q And just for the record, this is a</p> <p>6 document which previously was marked for</p> <p>7 identification as P-645.</p> <p>8 (Exhibit No. 78 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q So this is another shot of the</p> <p>12 website -- of the NCI website, A Snapshot of</p> <p>13 Ovarian Cancer. Correct?</p> <p>14 A Yes.</p> <p>15 Q And if you look at the bottom of the</p> <p>16 page, it's dated October 14th, 2016, correct?</p> <p>17 A Yes.</p> <p>18 Q And if you look at the third full</p> <p>19 paragraph, again it identifies the use of talc as</p> <p>20 a risk factor, correct?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Yes.</p> <p>23 MR. LOCKE: Lack of foundation, scope,</p> <p>24 form, and it's one page of six.</p> <p>25 MS. FRAZIER: Join.</p>	<p>1 heard that, that any of those other risk factors</p> <p>2 are in dispute?</p> <p>3 MR. LOCKE: Objection. Beyond the</p> <p>4 scope.</p> <p>5 THE WITNESS: No. I -- I've never heard</p> <p>6 of tall height before, but that's just me.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q But at least of -- again, this is dated</p> <p>9 December 13th, 2017, on the Snapshot of Ovarian</p> <p>10 Cancer, the NCI identifies the use of talc as a</p> <p>11 risk factor, correct?</p> <p>12 MR. LOCKE: Same objection.</p> <p>13 MR. DUFFY: Beyond the scope.</p> <p>14 MS. FRAZIER: Same objection.</p> <p>15 THE WITNESS: That's what it says.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q And so if I understand your -- your</p> <p>18 testimony correctly, you have never seen any of</p> <p>19 these PDQs before, correct?</p> <p>20 A I think at some point I probably saw a</p> <p>21 PDQ. I can't remember when or -- or what. Again,</p> <p>22 we -- we didn't have any contact at all with NCI</p> <p>23 or any connection, but I know I heard about it at</p> <p>24 some point.</p> <p>25 Q Okay. And -- and did you -- did you</p>
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<p>1 BY MR. GOLOMB:</p> <p>2 Q Okay. Let's go to the next document.</p> <p>3 MR. GOLOMB: What's the number of this?</p> <p>4 MR. LOCKE: 79.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Okay. This is Exhibit 79.</p> <p>7 (Exhibit No. 79 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. GOLOMB:</p> <p>10 Q Again, this is another Snapshot of</p> <p>11 Ovarian Cancer, which -- in which it continues to</p> <p>12 identify the use of talc as a risk factor,</p> <p>13 correct?</p> <p>14 A Along with --</p> <p>15 MR. LOCKE: Objection. Same as before,</p> <p>16 lack of foundation, form, beyond the scope, and</p> <p>17 it's one page of six.</p> <p>18 MS. FRAZIER: Join.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Correct?</p> <p>21 A Along with many other factors, yes.</p> <p>22 Q Okay. But the use of talc is a factor?</p> <p>23 A It is listed there.</p> <p>24 Q Okay. So I don't think anybody is</p> <p>25 disputing any of the other risk factors. Have you</p>	<p>1 learn at some point that after December 13th,</p> <p>2 2017, that the NCI took the use of talc off of its</p> <p>3 website?</p> <p>4 A I couldn't have told you what the date</p> <p>5 was, but at some point I did learn that it was not</p> <p>6 listed there.</p> <p>7 Q And how did you learn that?</p> <p>8 A I have no recall. Again, we didn't -- I</p> <p>9 mean, someone must have mentioned it to me at some</p> <p>10 point or -- yeah, I don't know.</p> <p>11 Q Okay. And did you learn about -- did</p> <p>12 you know about its proximity to one of the trials</p> <p>13 in this case?</p> <p>14 A No.</p> <p>15 Q Okay. So until I -- I'm telling you</p> <p>16 now, you were unaware that the NCI took the use of</p> <p>17 talc off of its website just days before a trial</p> <p>18 in one of these cases?</p> <p>19 MR. LOCKE: Objection.</p> <p>20 MS. FRAZIER: Object to form.</p> <p>21 MR. LOCKE: Beyond the scope.</p> <p>22 And just for the record, PCPC wasn't a</p> <p>23 defendant in that trial.</p> <p>24 THE WITNESS: No, I did not know that.</p> <p>25 BY MR. GOLOMB:</p>

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<p>1 Q Okay. So as you sit here today, you 2 recall that the NCI removed it from its website. 3 You don't remember how you -- how you learned 4 that, and you don't know how that got off the 5 website. Is that your testimony? 6 A Correct. 7 Q Okay. Let's talk about the Talc 8 Interested Party Task Force. And I -- we've 9 talked a lot about this in the last deposition, 10 and so I'm going to try not to repeat myself. 11 But to be clear, there are various 12 records, some of which -- most of which refer to 13 the Talc Interested Party Task Force, some of 14 which refer to the Interested Party Task Force. 15 They're one and the same; is that correct? 16 A That's correct. 17 Q Do you know when the task force was 18 created? 19 A I believe it was created in 19 -- maybe 20 '71, or early '70s. 21 Q And why was it created? 22 A In response to the finding of asbestos 23 or the reporting of asbestos in talc. 24 Q Okay. Well, was it the reporting of 25 asbestos or was it the reporting of talc in the</p>	<p>1 reports, and I know there was some question as to 2 what was actually found, but there were reports, I 3 believe in the newspaper, from findings out of -- 4 I think it was Mount Sinai Hospital or -- anyway, 5 of the finding of asbestos in talc. 6 Q And that was -- was that the finding of 7 asbestos in talc, that talc specifically being 8 found in the ovarian tissue? 9 A No. I thought it was just talc being 10 found in -- excuse me -- asbestos being found in 11 talcum products. 12 Q Just generally? 13 A Yes. 14 Q All right. And so you don't have a 15 recollection one way or the other as to what the 16 Henderson study concluded? 17 A My recollection of the Henderson study 18 is that they were reporting the finding of talc in 19 ovaries, but I believe they also found them in 20 controlled women that hadn't been exposed to talc. 21 So it was -- 22 Q Okay. And as you sit here today, do you 23 know one way or the other as to whether or not 24 the -- the Talc Interested Party Task Force was 25 created before or after the Henderson study?</p>
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<p>1 ovarian tissue? 2 A I thought it was the reporting of 3 asbestos. 4 Q All right. You -- you were asked 5 earlier by Mr. Tisi about the association between 6 talc and ovarian cancer, and I think -- correct me 7 if I'm wrong, I think you said that you -- that 8 "you," meaning PCPC, CFTA -- first learned about 9 that potential association in 1982 after the 10 Cramer study. Was that your testimony? 11 A I believe that's correct, yes. 12 Q Are you familiar with the Henderson 13 study? 14 A I do know what you are talking about, 15 yes. 16 Q And that was in the early '70s, correct? 17 A That sounds right. 18 Q All right. Was the Talc Interested 19 Party Task Force formed in response to the 20 Henderson study? 21 A I believe it was formed in response to 22 the asbestos finding. 23 Q All right. And when you say "asbestos 24 finding," what are you referring to? 25 A Well, I'm referring to the newspaper</p>	<p>1 MR. LOCKE: Objection. Asked and 2 answered. 3 THE WITNESS: As far as I'm aware, it 4 was created in response to the asbestos issue. 5 BY MR. GOLOMB: 6 Q Okay. Well, that -- but that wasn't my 7 question. My question was, do you know one way or 8 the other as you sit here today -- because you 9 don't -- you don't know the chronology of the -- 10 the asbestos finding and the Henderson study, 11 correct? 12 MR. LOCKE: Objection. 13 THE WITNESS: Yeah, I don't know the 14 year of the Henderson study. 15 BY MR. GOLOMB: 16 Q Right. But my question to you is a very 17 specific one, and that is, do you have a 18 recollection one way or the other as to whether or 19 not the Talc Interested Party Task Force was 20 created in response to the Henderson study? 21 MR. LOCKE: Objection. Asked and 22 answered. 23 THE WITNESS: What's the question? Was 24 it in response -- 25 MR. GOLOMB: Can you read back the</p>

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<p>1 question, please.</p> <p>2 THE WITNESS: I believe no.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Okay.</p> <p>5 A I believe it was created in response to</p> <p>6 the asbestos issue.</p> <p>7 Q And when you say "in response," what was</p> <p>8 the purpose of it?</p> <p>9 A To address -- when there was the</p> <p>10 finding, it was to look further into that to see</p> <p>11 if it was real, and then ultimately to come up</p> <p>12 with a specification so that -- to confirm that</p> <p>13 there was no asbestos in talc.</p> <p>14 Q And -- and how is -- how is a task force</p> <p>15 like that created?</p> <p>16 A So in general, if you -- I mean, if</p> <p>17 there's a finding, then basically we inform our</p> <p>18 members, and we look for interest in pursuing some</p> <p>19 activities related to a -- a particular issue.</p> <p>20 And in those -- those people again would, on their</p> <p>21 own then, that would be the group that would</p> <p>22 decide where do we go from here, what do we do.</p> <p>23 Q Okay. So it comes from you, meaning the</p> <p>24 PCPC, rather than the members coming to you and</p> <p>25 saying, you know, I just read something, this may</p>	<p>1 could where we think we might have members who are</p> <p>2 interested, should know about this, and then see</p> <p>3 if they're interested in again, you know, taking</p> <p>4 on further activities related to a particular</p> <p>5 topic.</p> <p>6 Q And when you say "further activities,"</p> <p>7 what kind of activities?</p> <p>8 A It totally depends on what the task</p> <p>9 force is. Like I say, in the case of the talc-</p> <p>10 asbestos issues, then it was putting together a</p> <p>11 specification -- or, rather, there was a talc</p> <p>12 specification, but adding in asbestos -- asbestos</p> <p>13 to that specification and working on methods to --</p> <p>14 for protection.</p> <p>15 Q And one of the, as you say, further</p> <p>16 activities is the hiring of scientists, correct?</p> <p>17 A Well, it could be.</p> <p>18 Q Right. And it was in the case of the</p> <p>19 talc -- the talc task force, correct?</p> <p>20 A I'm not sure what you mean by "hiring of</p> <p>21 scientists."</p> <p>22 Q Well, at some point in time in the -- in</p> <p>23 response to the Citizens Petition, in response to</p> <p>24 the NTP preliminary findings, the members of the</p> <p>25 PCPC at that time, the CFTA, who were also a</p>
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<p>1 be something that we need to create a task force</p> <p>2 for?</p> <p>3 A Oh, no, it depends. It can go either</p> <p>4 way. It can be us finding something. It's</p> <p>5 basically -- what our role would be then to</p> <p>6 disseminate that information to see if there is</p> <p>7 interest in forming a task force and -- and taking</p> <p>8 on further activities.</p> <p>9 Q Okay. And in the case of the Talc</p> <p>10 Interested Party Task Force, was that something</p> <p>11 where the -- the CFTA went through its members or</p> <p>12 one of its members came to the CFTA?</p> <p>13 A I think I'd have to say I don't know.</p> <p>14 Q Did you go back and -- there's minutes</p> <p>15 of these -- of these meetings, right?</p> <p>16 A Yes.</p> <p>17 Q So let me ask you generally, when the</p> <p>18 idea is created to -- to create a task force, how</p> <p>19 is it then implemented?</p> <p>20 A We would go out to -- in general, and</p> <p>21 this is -- since this was years before, it's going</p> <p>22 to be a little bit of a different setup that I'm</p> <p>23 not going to be aware of, but we would go out to</p> <p>24 committees where we think there might be interest,</p> <p>25 we would try to spread the word as widely as we</p>	<p>1 member of the Talc Interested Party Task Force,</p> <p>2 funded the hiring of scientists and experts to</p> <p>3 defend them in front of the NTP and to respond to</p> <p>4 the -- to the Citizens Petition, correct?</p> <p>5 A That can be one of the activities that</p> <p>6 we undertake, yes.</p> <p>7 Q But it's --</p> <p>8 A It can be doing a study, it could be</p> <p>9 hiring a scientist or hiring a consultant, I</p> <p>10 guess, to look at an issue.</p> <p>11 Q Okay.</p> <p>12 A It could be any number of things.</p> <p>13 Q Okay. And -- and I think we can agree</p> <p>14 that the -- the funding of the -- these task</p> <p>15 force, and the talc task force in particular, is</p> <p>16 not your bailiwick, so to speak, correct?</p> <p>17 A Yes. I mean -- I mean, I could speak</p> <p>18 generally to funding of task forces. I mean,</p> <p>19 obviously depending on how much funding is</p> <p>20 available and where people's level of interest in</p> <p>21 helps define what your future activities are.</p> <p>22 Q No, but I -- I understand that. But my</p> <p>23 question is, if I were to ask you specific</p> <p>24 questions about the funding of the talc task</p> <p>25 force, that is not your bailiwick.</p>

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<p>1 A That was Mark Pollack.</p> <p>2 Q Right. And so were you -- were you ever</p> <p>3 shown the -- the chart that Mr. Pollack created</p> <p>4 for us where -- for this litigation which</p> <p>5 identifies how much was deposited into the account</p> <p>6 of the Talc Interested Party Task Force over the</p> <p>7 years?</p> <p>8 A I think I've seen that, yes.</p> <p>9 Q Okay. And so that was somewhere close</p> <p>10 to half a million dollars, correct?</p> <p>11 A I mean that -- that sounds about right.</p> <p>12 Q And about 67 percent of that was funded</p> <p>13 specifically by J&J and Imerys and the</p> <p>14 predecessors of Imerys, correct?</p> <p>15 A That's what I heard this morning, yes,</p> <p>16 and that sounds right, consistent.</p> <p>17 Q And I think you said something -- that</p> <p>18 there were something like 18 or 20 different</p> <p>19 members of the task force.</p> <p>20 A I'm not sure there's -- I don't think</p> <p>21 there was more than that, but there was probably</p> <p>22 close to that. Fifteen.</p> <p>23 Q All right. And so the other 16 or so</p> <p>24 members of the task force put up a third of the</p> <p>25 funding, and Imerys and J&J put up the balance?</p>	<p>1 Q Well, as you -- as you said in your --</p> <p>2 your testimony just earlier today, the -- you see</p> <p>3 this -- whether it was the Henderson study or what</p> <p>4 you said was that asbestos was found in the talc,</p> <p>5 that the -- the CFTA then went to its members to</p> <p>6 determine the level of interest for a task force,</p> <p>7 correct?</p> <p>8 A I said that --</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: Yeah, I said that's how</p> <p>11 generally it works. I mean, I'm not sure exactly</p> <p>12 how that happened. But, yes, we -- we would want</p> <p>13 to inform our members, because that's one of the</p> <p>14 things we do, inform them what issues might be</p> <p>15 related to them, and then we would generally</p> <p>16 spread the word, is there interest, is there</p> <p>17 something that, you know, we should form a task</p> <p>18 force for. So I assume that's the way it went</p> <p>19 there basically.</p> <p>20 BY MR. GOLOMB:</p> <p>21 Q And people you think may be interested</p> <p>22 are then in some form or fashion contacted?</p> <p>23 A Well, we would contact -- now -- now</p> <p>24 certainly -- again, things were a little different</p> <p>25 back then, but now we would contact through our</p>
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<p>1 A That -- that could be.</p> <p>2 Q Okay. And once the task force is -- is</p> <p>3 created, what happens next?</p> <p>4 A Well, I mean, then they would get</p> <p>5 together and talk about it, and what activities do</p> <p>6 we undertake, what do we understand about this,</p> <p>7 what questions, is there -- you know, what</p> <p>8 follow-up is needed to understand what the issue</p> <p>9 is, and where do we go from here. And then if it</p> <p>10 comes to things that cost money, then it was like</p> <p>11 going out and getting proposals or -- and seeing</p> <p>12 what people want to do.</p> <p>13 Q Okay. And what happened in this case,</p> <p>14 in the case of the Talc Interested Party Task</p> <p>15 Force? When -- when was it first discussed</p> <p>16 amongst its members?</p> <p>17 A Are you talking about 1971 when it was</p> <p>18 first formed?</p> <p>19 Q Well, if that's when it was.</p> <p>20 A I mean, then there were discussions</p> <p>21 ongoing about asbestos, and we need methodologies</p> <p>22 so we can detect if there's asbestos in talc,</p> <p>23 and -- and there was a great deal of activity</p> <p>24 related to that, which included FDA activities as</p> <p>25 well.</p>	<p>1 committees. We have a Safety and Regulatory</p> <p>2 Toxicology Committee. It's a very large committee</p> <p>3 with a very large mailing list, so that gets to a</p> <p>4 lot of people. We have a Scientific Advisory</p> <p>5 Executive Committee now, it now has a different</p> <p>6 name, but -- and again, there would be more people</p> <p>7 we would contact. So we would make sure we spread</p> <p>8 the word because we're just trying to make sure</p> <p>9 everybody knows what's going on and see if they</p> <p>10 have interest.</p> <p>11 Q And then at some point, whether it's</p> <p>12 1971 or the way you do it now, once you assess</p> <p>13 those responses, you have a meeting of some sort,</p> <p>14 whether it's in person or telephone. Correct?</p> <p>15 A Generally, right, we -- then once we had</p> <p>16 identified interested people, then we would want</p> <p>17 to get that group together.</p> <p>18 Q Okay. And then the -- those interested</p> <p>19 parties are identified, some employees of the CFTA</p> <p>20 at the time are then kind of the ones in charge of</p> <p>21 having that liaison with the members on that</p> <p>22 particular task force, correct?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Yes. Somebody -- somebody</p> <p>25 would -- from the association would be involved.</p>

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<p>1 BY MR. GOLOMB:</p> <p>2 Q Okay. And when this -- when this task</p> <p>3 force was first created, who was that person from</p> <p>4 the CFTA?</p> <p>5 A I believe it was -- at the time I think</p> <p>6 we only had one science person, so it was Norm</p> <p>7 Estrin.</p> <p>8 Q I'm sorry?</p> <p>9 A Norm Estrin, I believe.</p> <p>10 Q And then there was -- there was in some</p> <p>11 form or fashion a meeting held of the prospective</p> <p>12 interested parties?</p> <p>13 A Yes. I mean, I looked at a lot -- a lot</p> <p>14 of minutes and there were a lot of meetings held.</p> <p>15 Q Okay. Did you see minutes from the --</p> <p>16 from back -- dating back to 1971?</p> <p>17 A I don't know about '71.</p> <p>18 Q Well, when was the first --</p> <p>19 A I saw them back to the '70s.</p> <p>20 Q Okay. Because I'll represent to you</p> <p>21 that the first meeting minutes that we have which</p> <p>22 refers to the, quote, ad hoc talc task force is</p> <p>23 1982.</p> <p>24 Were there minutes before that?</p> <p>25 A I know I saw documents relating to</p>	<p>1 Q Okay. I'm showing you Exhibit 80, which</p> <p>2 is the cover page of those minutes.</p> <p>3 Take -- take whatever time you need just</p> <p>4 to read that.</p> <p>5 A (Peruses document.) Okay.</p> <p>6 Q Okay. Now, when you have a -- a task</p> <p>7 force like this, is somebody appointed as a -- as</p> <p>8 a chairman of sorts of the committee?</p> <p>9 A It depends. Sometimes yes, sometimes</p> <p>10 no.</p> <p>11 Q What does it depend on?</p> <p>12 A The nature of the committee, the people</p> <p>13 who are on it.</p> <p>14 Q Okay. And do you recall in -- in this</p> <p>15 particular case whether or not a chairman was</p> <p>16 nominated and then agreed to?</p> <p>17 A You know, I recall in the case of going</p> <p>18 back to the '70s when the specifications was going</p> <p>19 on, I think there was a chair for that effort</p> <p>20 around developing methodology. I think there was</p> <p>21 also a chair on kind of the more overarching talc,</p> <p>22 not the -- I know I'm not answering your question.</p> <p>23 I'm just trying to think here.</p> <p>24 Do I recall if there was one here? I</p> <p>25 guess I'd have to say I don't recall.</p>
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<p>1 working on specifications. I thought they were</p> <p>2 minutes. Maybe I'm wrong, but I know I saw</p> <p>3 documents relating to that.</p> <p>4 Q Okay. And the date of the first task</p> <p>5 force minutes, which I'll show you in a minute,</p> <p>6 are dated November 11th, 1982. Do you recall</p> <p>7 seeing minutes from November 11th, 1982?</p> <p>8 A I wouldn't recall a precise date. I</p> <p>9 know that there were minutes going into the '80s,</p> <p>10 and that would have been after the Cramer study.</p> <p>11 So...</p> <p>12 Q Right. And that's -- that was my next</p> <p>13 question. That is a date which coincides shortly</p> <p>14 after the Cramer study.</p> <p>15 A Okay.</p> <p>16 Q So is that consistent with your</p> <p>17 recollection that there was minutes of the ad hoc</p> <p>18 talc task force shortly after the Cramer study was</p> <p>19 published?</p> <p>20 A I know that there was definitely -- that</p> <p>21 the task force got together after the Cramer study</p> <p>22 was published, yes.</p> <p>23 (Exhibit No. 80 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. GOLOMB:</p>	<p>1 Q Okay. Is it -- is it consistent with</p> <p>2 your recollection that there was maybe some</p> <p>3 activity surrounding the asbestos issue in 1971,</p> <p>4 and then no longer activity until 1982, when the</p> <p>5 Cramer study came out?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: No, there was activity in</p> <p>8 the '70s relating to the asbestos and development</p> <p>9 of -- of methodology that went well into the '70s.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q Okay. And would there have been various</p> <p>12 meetings in the '70s, whether they were by</p> <p>13 telephone or in person?</p> <p>14 A I believe that's correct, yes.</p> <p>15 Q And are -- whether the meeting is held</p> <p>16 by telephone or in person, are there minutes of</p> <p>17 those meetings?</p> <p>18 A Again, I'm -- I mean, I've seen things</p> <p>19 on developments of them. Were they minutes or</p> <p>20 were they otherwise memos? Off the top, I don't</p> <p>21 know. I thought they were minutes. I could be</p> <p>22 wrong.</p> <p>23 Q Okay. And was a -- was a chairman of</p> <p>24 this particular committee appointed before</p> <p>25 November 11th, 1982?</p>

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<p>1 A Well, if there's a chairman appointed on</p> <p>2 the asbestos -- on the earlier work, that doesn't</p> <p>3 mean that would be the same chairman in 1982.</p> <p>4 Q Okay. And do you know who Dr. Bruce</p> <p>5 Semple is?</p> <p>6 A I think I've heard the name. He's at --</p> <p>7 I want to say P&G.</p> <p>8 Q I'm sorry?</p> <p>9 A I want to say Procter & Gamble, but I</p> <p>10 could be wrong.</p> <p>11 Q Okay. Well --</p> <p>12 A Only because I've seen the name. I</p> <p>13 don't believe I've met the person because that</p> <p>14 would have been too long ago.</p> <p>15 Q If I told you there's a document that</p> <p>16 says: "On November 11, 1982, nominations were</p> <p>17 taken from the committee to elect a chairman.</p> <p>18 After discussion, the task force agreed to elect a</p> <p>19 chairman and a vice-chairman. Dr. Bruce Semple</p> <p>20 from Johnson & Johnson was unanimously elected</p> <p>21 chairman. Dr. Edward Jackson from Knoxville was</p> <p>22 unanimously elected vice-chairman."</p> <p>23 Would that refresh your recollection?</p> <p>24 MR. LOCKE: Objection. Let the record</p> <p>25 reflect that counsel is reading from pages that</p>	<p>1 A Yes.</p> <p>2 Q All right. And you -- you told us</p> <p>3 earlier that you read the various minutes of this</p> <p>4 committee to prepare for your deposition, correct?</p> <p>5 A I read some minutes from this committee,</p> <p>6 yes, or this task force.</p> <p>7 Q All right. And generally -- I'm sorry?</p> <p>8 A Task force, I guess we call it.</p> <p>9 Q Right. And generally, what was the goal</p> <p>10 of the task force back in November of 1982?</p> <p>11 A Well, I think just from the minutes, it</p> <p>12 was -- the concern was the ovarian cancer issue,</p> <p>13 just given that the study had come out, the Cramer</p> <p>14 study. And I know in minutes I've seen, and this</p> <p>15 refers to them, a thought of doing a study to look</p> <p>16 at translocation. So I think that was certainly</p> <p>17 one of the big discussion points.</p> <p>18 Q Okay. And when you say "look at</p> <p>19 translocation," what do you mean?</p> <p>20 A Trans -- talc can translocate from the</p> <p>21 perineum to the ovary.</p> <p>22 Q Okay. And what was -- what was done by</p> <p>23 the CFTA back in 1982 in conjunction with the task</p> <p>24 force to address that issue?</p> <p>25 A So there were -- I think it was actually</p>
Page 717	Page 719
<p>1 have not been shown to the witness, probably of</p> <p>2 the very same minutes that we're seeing the cover</p> <p>3 page of.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q I will refer you to page 2, subsection 4</p> <p>6 under Administrative Chairman, and take a look at</p> <p>7 that and tell me if I read that accurately.</p> <p>8 A Yes, you read it accurately.</p> <p>9 Q Thank you.</p> <p>10 Who is H. Joseph Sekerke, Ph.D.?</p> <p>11 A He is a -- was a CTFA employee</p> <p>12 scientist.</p> <p>13 Q Okay. So would he have been that person</p> <p>14 that liaison that we discussed earlier of this</p> <p>15 particular committee in 1982?</p> <p>16 A I think that would be likely.</p> <p>17 Q Okay. And that's who these minutes were</p> <p>18 signed by -- he just writes "Joe," Joe Sekerke.</p> <p>19 A It makes sense. I mean, it -- again,</p> <p>20 the science staff was very small at that point, so</p> <p>21 that was up from one to two at least. So that</p> <p>22 makes sense.</p> <p>23 Q Okay. And you mentioned that in -- in</p> <p>24 1982, we agree that Dr. Semple was the chairman of</p> <p>25 this committee, correct?</p>	<p>1 two studies, although I think one was kind of a</p> <p>2 beginner study leading to a bigger study with</p> <p>3 monkeys using radio tracers, I think three</p> <p>4 different radio tracers, that was implanted in the</p> <p>5 monkey vaginas, and it was -- then it was assessed</p> <p>6 whether they could -- the talc would translocate</p> <p>7 to the ovary.</p> <p>8 Q Okay. And then what was done next by</p> <p>9 the task force or any of its members?</p> <p>10 A I -- I don't know what you mean.</p> <p>11 Q Well, do you know one way or the other</p> <p>12 as to whether or not any of the members were then</p> <p>13 sent out to go talk to Dr. Cramer about his -- his</p> <p>14 paper?</p> <p>15 A I'm not sure. If you can show me</p> <p>16 documents that can refresh my memory.</p> <p>17 Q Well, I'm just asking you, based on your</p> <p>18 understanding as you sit here today whether or not</p> <p>19 Dr. Semple went to go talk to Dr. Cramer?</p> <p>20 A I don't remember. I mean, I may well</p> <p>21 have looked at those documents. I just don't</p> <p>22 remember.</p> <p>23 Q Okay. And what else in the 1980s did</p> <p>24 the task force do?</p> <p>25 A 1980s -- sorry. I just need to think.</p>

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<p>1 I -- I don't remember. I mean, I know 2 that was the big study that was done. 3 Q I'm sorry. 4 A That was the big study that was done. 5 Again, if you show me documents to refresh my 6 memory, that would be -- 7 Q All right. And is it fair to say that 8 whether it's the -- the Talc Interested Party Task 9 Force or any other task force, that they don't 10 necessarily meet on a regular basis, but they meet 11 kind of depending on the activity of the -- that 12 would be interesting -- interested to the task 13 force? 14 A That is correct, particularly with the 15 task force. We have some standing committees that 16 meet regularly, but task force, almost by 17 definition, are responding to specific issues. 18 Q Okay. So do you know one way or on the 19 other as to whether or not there was a meeting of 20 the task force between November 11th, 1982, and 21 September 16th of 1993, which I'll represent to 22 you is the -- I'm sorry -- February 2nd, 1993, 23 which is -- I'll represent to you is the -- the 24 next minutes that we have? 25 MR. LOCKE: Objection.</p>	<p>1 his paper was circulated to the members of the 2 task force before it was published? 3 A I believe it was. 4 Q Okay. And is it -- is it your -- your 5 experience that that is a -- is an ethical 6 approach to the publication of a paper, to 7 circulate it to people who have a financial 8 interest in the outcome of the paper before it's 9 published in a scientific journal? 10 MR. LOCKE: Objection to form and beyond 11 the scope. 12 THE WITNESS: What -- what we -- the 13 comments that we're looking for are typos, 14 clarity. We can't question the conclusion of the 15 authors, and when we're hiring ethical people, 16 they're not going to let us do that. 17 BY MR. GOLOMB: 18 Q Okay. So then -- so you have -- you -- 19 the task force meets. They agree on an approach, 20 in this case the approach is to -- is to contact 21 and retain Dr. Gross, give Dr. Gross kind of his 22 marching orders of what he is going to do. He 23 goes out and does it. The -- the money is then 24 funded by the task force comes from your 25 organization. It's then circulated, and you meet</p>
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<p>1 THE WITNESS: I -- I don't know. 2 BY MR. GOLOMB: 3 Q All right. Do you know, based on your 4 recollection of your preparation for this 5 deposition, as to whether or not there was 6 something that was going on between 1982 and 1992 7 that would have interested the task force? 8 A I mean, I think -- I think there were 9 papers that were looked at, but I couldn't be more 10 specific than that at this point. Again -- 11 Q Papers looked at by whom? 12 A I think there may have been ovarian 13 cancer papers that were looked at. But again, if 14 you can show me something to -- to help my memory, 15 that would be great, but -- I know there were big 16 things going on in '93, but -- 17 Q Okay. And then as -- as you were 18 questioned earlier today by Mr. Tisi, Dr. Gross 19 was then hired in 1993, correct? 20 A Was that '93? Yes. 21 Q All right. And that's when he -- he 22 published his meta-analysis, correct? 23 A Yes. 24 Q And do you know one way or the other as 25 to whether or not Dr. Gross's paper or draft of</p>	<p>1 to discuss the -- the -- what potential 2 typographical errors. Is that your testimony? 3 MR. LOCKE: Objection to form. 4 THE WITNESS: No, that wasn't my 5 testimony. I guess it would just be helpful if I 6 could see the documents. 7 I mean, we -- when we -- when we hire a 8 consultant, yes, we do look at -- and there are 9 areas that we have -- industry has knowledge that 10 a consultant may not. We're hiring -- for 11 example, if we're hiring somebody who is an expert 12 epidemiologist, we can't question his epi- -- 13 their epidemiology findings, but we may have more 14 knowledge about how talc is used by a consumer, 15 how -- you know, questions about analysis of talc, 16 purity of talc, mining, mineralogy. 17 So we're reviewing it as -- with some 18 expertise, and as well as saying, you know, if we 19 get a document back and we think there could be 20 more clarity, I mean, I think it's okay to say to 21 an author, Could you clarify a little more what 22 you mean here. 23 BY MR. GOLOMB: 24 Q Well, does the -- does the document -- 25 once the -- once the draft from the outside expert</p>

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<p>1 is -- is written, does that paper then go to the</p> <p>2 CTFA or does it go to one of the members?</p> <p>3 A Typically -- typically it would go -- if</p> <p>4 CTFA is the one, or PCPC, is arranging that, then</p> <p>5 it would come back to us, and then we would</p> <p>6 distribute it to the task force.</p> <p>7 Q Okay. Have you ever seen a situation</p> <p>8 where an expert was hired and the draft went to an</p> <p>9 industry member before it went to -- to the CTFA</p> <p>10 and was circulated to its members?</p> <p>11 A Only --</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Only the one we talked</p> <p>14 about this morning.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Which one was that?</p> <p>17 A The Huncharek/Muscat review.</p> <p>18 Q Okay. Let me show you the next</p> <p>19 document.</p> <p>20 MR. GOLOMB: This is Exhibit 81.</p> <p>21 (Exhibit No. 81 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. GOLOMB:</p> <p>24 Q And for the record, this is a memorandum</p> <p>25 dated September 22nd, 1993, from Stephen Gettings,</p>	<p>1 A I -- I don't know.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q If you just read the second paragraph,</p> <p>5 you'll see: "It has been proposed that we arrange</p> <p>6 for Dr. Gross to publish his analysis." Do you</p> <p>7 see that?</p> <p>8 A Yes.</p> <p>9 Q And then the next sentence says:</p> <p>10 "Johnson & Johnson will arrange for preparation of</p> <p>11 a first draft, which will then be reviewed by the</p> <p>12 task force." Correct?</p> <p>13 A Yes.</p> <p>14 Q Okay. Is that the first time you've</p> <p>15 ever seen anything like that where a member -- an</p> <p>16 industry member gets the first draft of -- and</p> <p>17 then they circulate it?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 MS. FRAZIER: Object to form.</p> <p>20 THE WITNESS: Well, as I say, the one</p> <p>21 this morning would be the other one, but "will</p> <p>22 arrange for the preparation," so I guess they're</p> <p>23 the interface with the consultant. And then it</p> <p>24 will go to the task force. So I'm not sure if J&J</p> <p>25 is reviewing the draft. They're arranging for the</p>
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<p>1 Ph.D., to the Talc Interested Party Task Force.</p> <p>2 First of all, let me just ask you for</p> <p>3 the record, Dr. Gettings was the director of</p> <p>4 toxicology at that time, correct?</p> <p>5 A Yes.</p> <p>6 Q And was there overlap between</p> <p>7 Dr. Gettings being the director of toxicology and</p> <p>8 the time that you came to the CTFA?</p> <p>9 A No.</p> <p>10 Q When did Dr. Gettings leave?</p> <p>11 A I -- well, I started in October of '97,</p> <p>12 and he left soon before then. He had actually</p> <p>13 moved over to the legal department and was there</p> <p>14 very briefly, and then he moved on to -- he went</p> <p>15 to a member company.</p> <p>16 Q And who replaced Dr. Gettings?</p> <p>17 A I did.</p> <p>18 Q All right. And so have you seen this</p> <p>19 document before?</p> <p>20 A I don't know. I want to say I don't</p> <p>21 think so.</p> <p>22 Q Okay. So this is a CF -- CFTA document</p> <p>23 dated September 22nd, 1993, and you did not see</p> <p>24 this in your preparation of now Day 3 of a</p> <p>25 deposition?</p>	<p>1 draft to be prepared is how I'm reading this.</p> <p>2 BY MR. GOLOMB:</p> <p>3 Q Okay. So that -- that's how you read</p> <p>4 "Johnson & Johnson will arrange for a preparation</p> <p>5 of a first draft"?</p> <p>6 A Probably, yeah. I don't -- I don't know</p> <p>7 for sure.</p> <p>8 Q So you don't -- as you sit here, you</p> <p>9 don't know one way or the other as to whether</p> <p>10 Johnson & Johnson received that first draft?</p> <p>11 A No.</p> <p>12 Q And if so, you don't know what happened</p> <p>13 to that first draft once it was reviewed by</p> <p>14 somebody at Johnson & Johnson and then circulated</p> <p>15 amongst the task force members, correct?</p> <p>16 MS. FRAZIER: Object to form.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Yeah, I don't know if J&J</p> <p>19 reviewed the draft, it went straight to the task</p> <p>20 force.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Okay. And then it says if you -- quote</p> <p>23 in big -- in capital letters, bold: "If you DO</p> <p>24 NOT AGREE with this proposed course of action,</p> <p>25 please contact me by close of business, COB,</p>

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<p>1 Monday, September 27th, 1993." Correct?</p> <p>2 A That's what it says, yes.</p> <p>3 Q And are you aware one way or the other</p> <p>4 as to whether or not anybody objected to that?</p> <p>5 A No, I would not be aware.</p> <p>6 Q And is it generally the -- the role at</p> <p>7 the CFTA at the time that they review any document</p> <p>8 before it's published?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I would say we -- we</p> <p>11 generally review documents before they're</p> <p>12 published, yes.</p> <p>13 BY MR. GOLOMB:</p> <p>14 Q Okay. And you told us one of the</p> <p>15 reasons why you do that is to -- for grammatical</p> <p>16 errors. Why else would you -- why else would the</p> <p>17 CFTA review publications of outside experts before</p> <p>18 they're published?</p> <p>19 A I guess, again, I would just say that</p> <p>20 there may be some expertise, some -- you know,</p> <p>21 again, more knowledge of -- if somebody is writing</p> <p>22 on talc, the industry knows best how it's used.</p> <p>23 If there is any question of how it's sourced, that</p> <p>24 kind of thing, whether it came up in this</p> <p>25 document, I don't know, but there are certain</p>	<p>1 gathers in some form or fashion, or maybe there's</p> <p>2 some leadership to the group, like Dr. Semple and</p> <p>3 some others, that say, Okay, this is reasonable,</p> <p>4 go ahead, and then the -- the CTFA can you tell us</p> <p>5 a check.</p> <p>6 A We do a contract, and we would be the</p> <p>7 ones who would pay, yes.</p> <p>8 Q Okay. Have you ever seen a situation</p> <p>9 where the -- the industry member pays for it</p> <p>10 themselves?</p> <p>11 A Not in my experience, that's not how</p> <p>12 it's worked.</p> <p>13 Q Okay. And why do you do it that way?</p> <p>14 Why do you have -- why is the money deposited into</p> <p>15 the CTFA, and then a check written from the CTFA</p> <p>16 to the expert, rather than the industry member pay</p> <p>17 for it themselves?</p> <p>18 A Because it's multiple industry members.</p> <p>19 So we're -- we're putting the industry resources</p> <p>20 together, so we're the site where the money is</p> <p>21 collected, and then we write one check to the</p> <p>22 consultant.</p> <p>23 Q Okay. Let me show you the next</p> <p>24 document.</p> <p>25 This is 82.</p>
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<p>1 areas of expertise. Yeah, we're hiring them for</p> <p>2 their epidemiology expertise.</p> <p>3 Q And do you -- do you know who it is that</p> <p>4 paid for Dr. Gross's report?</p> <p>5 A I believe we did.</p> <p>6 Q When you say "we," you mean the PCPC?</p> <p>7 A I'm sorry. PCPC, yes.</p> <p>8 Q At the time CTFA?</p> <p>9 A Yes.</p> <p>10 Q And that would be out of money that is</p> <p>11 deposited into the task force account?</p> <p>12 A Yes. That would be typical.</p> <p>13 Q The PCPC or its predecessor CTFA</p> <p>14 wouldn't go out of pocket to pay for something</p> <p>15 like this, right? They would ask its members</p> <p>16 first?</p> <p>17 A The activities of the interested</p> <p>18 parties, that's what they are -- that's what</p> <p>19 "interested party" refers to, people who are</p> <p>20 willing to expend money, because you have to do</p> <p>21 that to get certain things done.</p> <p>22 Q Okay. And that so the -- the task force</p> <p>23 members agree on a course of action, in this case</p> <p>24 the course of action was to hire Dr. Gross.</p> <p>25 Dr. Gross makes a proposal. The task force then</p>	<p>1 (Exhibit No. 82 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Now, this is a letter from Dr. Alfred</p> <p>5 Wehner, correct?</p> <p>6 A Yes.</p> <p>7 Q And it says it's cc'd to M. Chudkowski,</p> <p>8 correct?</p> <p>9 A Yes.</p> <p>10 Q Who is that?</p> <p>11 A Michael Chudkowski, he's a J&J person.</p> <p>12 Q And is there a reason why Mr. Chudkowski</p> <p>13 was the sole member of the task force that was</p> <p>14 copied on a letter from Dr. Wehner to Dr. Gettings</p> <p>15 in November of 1993?</p> <p>16 A I think I need to read it first.</p> <p>17 Q Okay.</p> <p>18 A (Peruses document.)</p> <p>19 I don't know. I don't know if \$1400 was</p> <p>20 the whole amount, and this to me looks like this</p> <p>21 is not the way we normally do things. Normally,</p> <p>22 the -- as I say, we pay them for an interested</p> <p>23 party. So I don't know why in this case J&J</p> <p>24 was -- as asked being to pay.</p> <p>25 Q Okay. Let's be clear about this. Well,</p>

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<p>1 first of all, based on the letter, J&J was not 2 asked to pay, correct? J&J volunteered to pay. 3 A Right. 4 MR. LOCKE: Objection. Form. 5 BY MR. GOLOMB: 6 Q Right. So it says: "While you" -- it 7 says: "I am enclosing" -- meaning Dr. Wehner, "I 8 am enclosing Dr. Gross's invoice in the amount of 9 \$1400 for his professional services and expenses. 10 While you mentioned, and Mike Chudkowski 11 confirmed, that J&J would pay the costs for the 12 manuscript preparation, I believe it to be 13 appropriate for BEC to submit the invoice to CTFA 14 because CTFA requested the job." Correct? 15 A That's what it says. 16 Q Right. So they are -- although J&J has 17 volunteered to pay the full costs, at least of 18 that particular invoice, doctor -- Dr. Wehner is 19 suggesting that the -- that the check be cut by 20 the intermediary, CTFA, rather than coming from 21 Johnson & Johnson itself, correct? 22 MR. LOCKE: Objection. 23 THE WITNESS: He's saying he's 24 submitting the invoice to CTFA. So he felt from 25 where he sat, it should come to CTFA.</p>	<p>1 the Hankinson study is. 2 A I know that Dr. Hankinson was an author 3 on a couple of different studies. She was -- she 4 was one of the coauthors on the Gertig study, but 5 she was also a coauthor on the Houghton study. 6 Q Okay. And which study -- if there was a 7 minutes draft -- draft of the minutes from January 8 of 1994, do you know which Hankinson study it 9 would be referring to? 10 A I don't. I'm trying to think what year 11 the Gertig study, and I'm -- I'm blanking on that. 12 (Exhibit No. 83 was marked for 13 identification.) 14 BY MR. GOLOMB: 15 Q Okay. Let me show you the Talc 16 Interested Party Task Force. Now, this is -- it 17 says "Draft Minutes." I'm not sure that we have 18 the final minutes, but it says "Draft Minutes," 19 dated January 11th, 1994. 20 Have you seen this before? 21 A I -- I can't recall exactly which 22 minutes I've seen. If I read it, it might seem 23 familiar, but... 24 Q Okay. Did -- did you read what you 25 thought were all of the minutes of the task force</p>
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<p>1 BY MR. GOLOMB: 2 Q The invoice? 3 A Because then he says he expects that 4 we're going -- that CTFA is going to forward the 5 invoice to J&J. 6 Q Well, it says: "When you forward the 7 invoice to J&J, please have them pay out the check 8 to Alan Gross and send it to them directly." 9 So J&J is paying directly. 10 A That's what it says, yes. 11 Q Okay. And that's why that letter was 12 copied to Mr. Chudkowski, right, because -- 13 A Yes. 14 Q -- he is with J&J, and J&J volunteered 15 to pay. 16 A Correct. So this is not, I would say, 17 the usual way that we pay. 18 Q In fact, you've never seen it done that 19 way before or since, correct? 20 MR. LOCKE: Objection. 21 THE WITNESS: I think that's true. 22 BY MR. GOLOMB: 23 Q Do you know what the Hankinson study is? 24 A What year does it refer to? 25 Q Well, I'm just asking if you know what</p>	<p>1 to prepare for your deposition? 2 A I read a lot of them. 3 Q Okay. 4 A This is why I thought Bruce Semple was 5 from Procter & Gamble because he moved over to it. 6 I think -- I believe I did read these. 7 Q Okay. And attached to that, which is 8 Bates-stamped J&J 15618, which is the second 9 page -- well, it's the second page of this 10 exhibit. It's the third page of the full 11 document. The second page just saying 12 "Adjournment" and the signature of Steve Gettings. 13 Do you see it says "Draft" on the next 14 page? 15 A I'm sorry. Oh, yes, it says "Draft." 16 Q First of all, how were -- how were these 17 minutes created? Why -- why are there draft 18 minutes? 19 A Again, this is before my time. I can 20 tell you how we do it now, but I think it was the 21 same then, is generally someone would draft 22 minutes, and then it would go out to the group so 23 people could look, and if they said, You know, I 24 remember this a little differently, or really you 25 should -- we talked about this too, and it doesn't</p>

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<p>1 seem to be here. Just so members would have a 2 chance to -- to input so that they were accurate. 3 Q Okay. And these minutes are dated 4 January 11th, 1994. And if you look at page 2, 5 one of the topics that was discussed was ovarian 6 cancer. Do you see that? 7 A Yes. 8 Q And it refers to the recent paper by 9 Dr. Hankinson, correct? 10 A Yes. 11 Q And under paragraph 2, it says "M. 12 Chudkowski." Again, Michael Chudkowski from J&J, 13 correct? 14 A Yes. 15 Q It says: "Agreed to contact Dr. Gross 16 to discuss incorporation of the results of the 17 Hankinson study in his meta-analysis manuscript." 18 Do you see that? 19 A Yes. 20 Q So in this case you have a -- what 21 was -- what was Mr. Chudkowski's title at J&J? 22 A Oh, I don't know. 23 Q Was he -- was he an executive of some 24 sort? 25 A I don't know. I think he was a</p>	<p>1 Q Okay. And do you know in this case how 2 the Hankinson study was identified? 3 A No, I don't. 4 Q And then there was a conference -- some 5 sort of conversation or communication between the 6 CTFA and the task force members about that study, 7 correct? 8 A Yes. 9 Q And Mr. Chudkowski then agreed to 10 contact Dr. Gross, who had been hired and was in 11 the process of drafting a -- essentially a report 12 in defense of the -- the industry from the 13 Citizens Petition that was filed in 1993, correct? 14 A Yeah, I think that's right. He was 15 doing a meta-analysis. So... 16 Q Okay. And do -- are you aware one way 17 or the other as to whether or not there were any 18 other studies that were published in that 19 intervening time between the time that Dr. Gross 20 was hired and the time that he finalized this 21 report? 22 A No, I'm not. 23 Q Okay. So you don't know one way or the 24 other as to whether or not there are other 25 reports, other papers other than the Hankinson</p>
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<p>1 scientist. I remember him being on phone calls, 2 but I'm not sure I ever knew his title. 3 Q What kind of scientist was he? 4 A I just know he participated on technical 5 phone calls, so... 6 Q All right. So a member of the -- an 7 industry member of the task force saw -- how was 8 the -- first of all -- strike that. 9 How was the Hankinson study distributed 10 amongst the task force members? 11 A The fact that it says this 94TA03, 12 that's -- that was what we used to use, a system 13 we used to use. We used to mail them out, so I -- 14 that would -- in '94, I think that would probably 15 be correct, and we would number them accordingly 16 sequentially. 17 Q Okay. So it would be somebody -- just 18 so we're clear on this, somebody from the CTFA in 19 their role as whatever they do at the CTFA, would 20 see the Hankinson study, and then the Hankinson 21 study would be circulated to the members of the 22 task force? 23 A It could be that. It also could be a 24 member bringing something to our attention that we 25 would circulate.</p>	<p>1 study, which in fact confirm the association 2 between talc and ovarian cancer; is that correct? 3 MR. LOCKE: Objection. 4 THE WITNESS: There's also -- there's 5 reference here to another study as well. 6 BY MR. GOLOMB: 7 Q Okay. Do you know one way or the other 8 as to whether or not that study confirms the 9 association between talc and ovarian cancer? 10 A I do not. 11 Q Okay. Are you -- are you familiar with 12 the NTP inhalation study? 13 A Yes. 14 Q And what did the NTP inhalation study 15 conclude? 16 A It concluded that talc -- inhaled talc 17 was carcinogenic to female rats, caused lung 18 cancer. There was no evidence of carcinogenicity 19 in male or female mice, and I believe it was 20 equivocal evidence in male rats. 21 Q Okay. And anything else? 22 A That they concluded? 23 Q Yeah. 24 A Well, that was the main point, I guess. 25 Q When was the last time you reviewed the</p>

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<p>1 NTP inhalation study?</p> <p>2 A I didn't review the report. I reviewed</p> <p>3 assessments of it.</p> <p>4 Q And did you review Dr. Gross's</p> <p>5 assessment?</p> <p>6 A I don't believe so.</p> <p>7 Q Okay. So just we're -- so we're clear,</p> <p>8 that study was in the early '90s, correct?</p> <p>9 A Yes.</p> <p>10 Q And it -- it may or may not have -- have</p> <p>11 had an effect on Dr. Gross's ultimate conclusions,</p> <p>12 correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, I don't recall</p> <p>15 that it did because it's not ovarian cancer.</p> <p>16 It's -- it's -- the NTP study is an inhalation,</p> <p>17 and it had to do with lung cancer and it was</p> <p>18 discussed at length at the ISRTP. So, I'm not</p> <p>19 sure that -- Dr. Gross, I believe, was doing on</p> <p>20 ovarian cancer.</p> <p>21 BY MR. GOLOMB:</p> <p>22 Q Okay. Is that something you're</p> <p>23 surmising, or is that something that you reviewed</p> <p>24 from the records?</p> <p>25 A I'm trying to remember about Dr. Gross's</p>	<p>1 and ovarian cancer, correct?</p> <p>2 A That's about right.</p> <p>3 Q Right. But this is a paper, the Gross</p> <p>4 paper was a paper that was where Dr. Gross was</p> <p>5 specifically retained by industry members of the</p> <p>6 CF -- CTFA. That's a little bit different than</p> <p>7 those other 30 papers, would you agree?</p> <p>8 A It is, yes.</p> <p>9 Q Okay. And so are you -- are you telling</p> <p>10 us that you looked at the Gross paper, reading it</p> <p>11 quickly with the same care that you did with the</p> <p>12 other more -- now more than 30 papers?</p> <p>13 MR. LOCKE: Objection. If you have a</p> <p>14 question about the Gross paper, ask the question.</p> <p>15 It's not a memory test. If you want to give her</p> <p>16 the paper, go ahead.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Can you answer my question?</p> <p>19 A Yeah, I'm happy to look at it, because</p> <p>20 again --</p> <p>21 Q Well, it's not a memory test. I'm just</p> <p>22 trying to -- my question is a very specific one</p> <p>23 about the -- not about the content of the paper</p> <p>24 but about the care in which you read the paper.</p> <p>25 MR. LOCKE: What difference does it</p>
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<p>1 review, but those are two very separate issues,</p> <p>2 so --</p> <p>3 Q Okay. Well -- all right. Have you --</p> <p>4 you have -- prior to preparing for your</p> <p>5 deposition, did you -- did you review the Gross</p> <p>6 paper?</p> <p>7 A I reviewed -- I mean, by reviewed it --</p> <p>8 Q Read it.</p> <p>9 A Read it quickly. I mean, there were</p> <p>10 drafts, and I -- I looked at it, and I -- I'm</p> <p>11 recalling them as being ovarian cancer.</p> <p>12 Q Okay. And did you read it in</p> <p>13 preparation for your deposition?</p> <p>14 A I read it quickly.</p> <p>15 Q Okay. When you say "read it quickly,"</p> <p>16 what does that mean?</p> <p>17 A I just mean there's a ton of papers out</p> <p>18 there, and I certainly am not claiming to -- as I</p> <p>19 sit here, that I read each and every one and could</p> <p>20 recall the details of them.</p> <p>21 Q Well, there's -- there's a ton of</p> <p>22 papers, and I think we -- we've already talked</p> <p>23 about the numbers. There are now in excess of 30</p> <p>24 papers that were -- were written by -- by various</p> <p>25 scientists to look at the association between talc</p>	<p>1 make?</p> <p>2 MR. GOLOMB: Well, that's rhetorical.</p> <p>3 THE WITNESS: Your question --</p> <p>4 MR. GOLOMB: I'm not here to answer</p> <p>5 questions.</p> <p>6 THE WITNESS: Your question, I thought,</p> <p>7 was about NTP bioassay, which was an inhalation</p> <p>8 assay looking at where lung tumors were found.</p> <p>9 The Gross paper was about ovarian cancer. So I --</p> <p>10 I don't think it's in there, but if you want to</p> <p>11 show me the paper and -- where that was opined on</p> <p>12 as well, maybe it was. I -- I just don't</p> <p>13 remember.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q All right. Well, you -- you said, and</p> <p>16 when I refer to "you," I'm referring to the CTFA,</p> <p>17 because you may not have been around at that</p> <p>18 point.</p> <p>19 A I wasn't.</p> <p>20 Q But the -- the draft -- in answer to</p> <p>21 Mr. Tisi's question earlier today, the draft of</p> <p>22 the -- the Gross paper was circulated amongst the</p> <p>23 industry members of the CTFA, correct?</p> <p>24 A That's correct.</p> <p>25 Q Right. And then it was reviewed by the</p>

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<p>1 CTFA members, and the CTFA members then forwarded</p> <p>2 comments. Correct?</p> <p>3 A I presume so. I didn't -- have not seen</p> <p>4 those comments.</p> <p>5 Q Okay. Let's take a look at the next</p> <p>6 exhibit.</p> <p>7 MR. LOCKE: Why don't we take a break.</p> <p>8 We've been going for an hour and --</p> <p>9 MR. GOLOMB: Sure.</p> <p>10 MR. LOCKE: -- almost 50 minutes. I</p> <p>11 think we've got about 44 minutes left.</p> <p>12 MR. GOLOMB: Okay.</p> <p>13 THE VIDEOGRAPHER: The time is 4:38 p.m.</p> <p>14 We're going off the record.</p> <p>15 (Recess.)</p> <p>16 THE VIDEOGRAPHER: The time is 4:49</p> <p>17 p.m., and we're back on the record.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q So we were -- we were talking about the</p> <p>20 NTP inhalation study. And correct me if I'm</p> <p>21 wrong, you -- you testified that they -- as far as</p> <p>22 you know, there would be no reason for that study</p> <p>23 to be included in the paper and analyzed within</p> <p>24 the paper.</p> <p>25 Am I summarizing your testimony</p>	<p>1 Q Okay. Well, we -- we've already --</p> <p>2 we've already gone through and -- and have agreed</p> <p>3 that the consultant is hired, the consultant is</p> <p>4 given marching orders on what to do, the</p> <p>5 consultant goes out and does it. The consultant</p> <p>6 then circulates the paper, whether it goes</p> <p>7 directly to an industry member, as it did in this</p> <p>8 case, or to the CTFA. It's then circulated to all</p> <p>9 the industry members, they edit it.</p> <p>10 Am I -- do I have it correct so far?</p> <p>11 MR. LOCKE: Objection to form.</p> <p>12 THE WITNESS: Well, I mean, they</p> <p>13 would -- I wouldn't say they edit it. They can</p> <p>14 comment on it, and then CTFA -- generally the CTFA</p> <p>15 liaison person or PCPC would compile comments, if</p> <p>16 that makes sense.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Okay. And would those comments include</p> <p>19 telling the scientists include this or don't</p> <p>20 include that?</p> <p>21 A I mean, in general, no. I mean, if they</p> <p>22 left off a -- didn't include a paper, for example,</p> <p>23 or something like that, it could be a -- you know,</p> <p>24 did you mean to exclude this paper or something</p> <p>25 like that, but I -- but in general --</p>
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<p>1 correctly?</p> <p>2 A As I recall, the --</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: The Gross paper, because</p> <p>5 it dealt with ovarian, and the -- and the NTP was</p> <p>6 inhalation lung cancer issue.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q Okay. So then I assume that there</p> <p>9 would -- then there wouldn't be any reason -- and</p> <p>10 based on what you told us before about kind of the</p> <p>11 subjects, how subjects are treated within a paper,</p> <p>12 and typographical or grammatical errors are edited</p> <p>13 or whatnot, there wouldn't be any reason for an</p> <p>14 industry member to tell the scientists what to</p> <p>15 include in the paper, would there?</p> <p>16 A You're talking about a consulting</p> <p>17 scientist?</p> <p>18 Q Yeah.</p> <p>19 A And would industry -- I mean, we would</p> <p>20 obviously up front say, This is what we want you</p> <p>21 to review.</p> <p>22 Q Right.</p> <p>23 A Or whatever -- whatever they're</p> <p>24 preparing it on. So I'm not sure what you mean by</p> <p>25 tell them --</p>	<p>1 Q What about -- what about the other --</p> <p>2 the vice versa of that, where they included a</p> <p>3 paper and would an industry member say, Huh-uh,</p> <p>4 take that one out?</p> <p>5 A Not -- I mean, not to better the</p> <p>6 results. You know, only if they included some</p> <p>7 topic that seemed really off topic. But, again,</p> <p>8 we're choosing our consultants carefully, so we</p> <p>9 don't think that's going to happen.</p> <p>10 Q Okay. But if -- but if that did happen,</p> <p>11 that would be a problem, wouldn't it?</p> <p>12 A If something were like poorly written or</p> <p>13 something, I mean, you could see where, of course,</p> <p>14 you could have a comment, but then you would have</p> <p>15 chosen your consultant wrong.</p> <p>16 Q Okay. But if -- if -- okay.</p> <p>17 And if -- but if the consultant was</p> <p>18 said -- told by an industry member, Include this</p> <p>19 but don't include that --</p> <p>20 A No.</p> <p>21 Q -- you would see an ethical problem in</p> <p>22 that if that happened?</p> <p>23 A Correct. I mean --</p> <p>24 MR. LOCKE: Objection. Beyond the</p> <p>25 scope.</p>

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<p>1 THE WITNESS: Right. If they're looking 2 at a topic, then they -- we would be hiring them 3 for their expertise, and they would be selecting 4 what -- what's relevant. 5 MR. GOLOMB: Okay. Can I have the next 6 document, please. 7 (Exhibit No. 84 was marked for 8 identification.) 9 BY MR. GOLOMB: 10 Q This is Exhibit 84. 11 This is a letter dated May 5th, 1994, 12 from Michael Chudkowski. Have you seen that 13 letter before? 14 A I don't think so. 15 Q So this is a letter on Johnson & Johnson 16 stationery dated May 4th, 1994, from Dr. Alan 17 Gross -- I mean to Dr. Alan Gross from -- 18 MS. FRAZIER: Do you have a copy of 19 that? 20 (A discussion was held off the record.) 21 BY MR. GOLOMB: 22 Q -- from Michael Chudkowski, manager of 23 preclinical evaluations. Do you see that? 24 A To Michael Chudkowski. 25 Q Do you see the signature line on the</p>	<p>1 the FDA to see the results of an animal study? 2 A Well, I think -- 3 MR. LOCKE: Same objection. 4 THE WITNESS: -- the FDA knows the 5 results of the animal study. That's not a 6 mystery. I think this is a publication, which 7 perhaps read poorly because it went over into 8 another totally different area. Nothing to do 9 with ovarian cancer, nothing to do with 10 epidemiology study. 11 BY MR. GOLOMB: 12 Q Okay. So you never talked to 13 Mr. Chudkowski about this, correct? 14 A No. 15 Q And you've never talked to Dr. Gross 16 about this? 17 A No. 18 Q So what -- you're surmising that they -- 19 he -- doctor -- Mr. Chudkowski wants to take the 20 rodent study out of the paper because it's saving 21 the FDA time -- 22 MR. LOCKE: Object -- 23 BY MR. GOLOMB: 24 Q -- because they already know about it? 25 MR. LOCKE: Objection. There's no</p>
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<p>1 bottom of the page? 2 A Yes, I do. 3 Q Okay. So it's a letter from Chudkowski 4 to Gross, correct? 5 A Yes. 6 Q And on the second full paragraph, it 7 says: "Prior to submission, however, please 8 delete any reference to the NTP inhalation studies 9 conducted in rodents." 10 Did I read that correctly? 11 A You did. And the reason for that would 12 be this is a paper -- this is exactly what I was 13 saying, that it's on ovarian cancer and talc 14 exposure, that's humans. Apparently he included 15 an inhalation study in rodents. That's really off 16 topic. So it's probably -- it doesn't -- it's not 17 relevant to the conclusion related to ovarian 18 cancer and talc exposure. 19 Q Well, so you're -- you're saying that 20 only the clinical aspect would be relevant to, in 21 this case, the FDA who is looking at a -- at a 22 Citizens Petition rather than some animal study? 23 MR. LOCKE: Objection. Form. 24 BY MR. GOLOMB: 25 Q You don't think it would be relevant for</p>	<p>1 evidence that CTFA saw this at this time. 2 THE WITNESS: And I -- I mean, the Gross 3 paper is not -- I mean, it's being published in a 4 journal. I -- I -- this is why I was asking 5 because I was confused why two, so different 6 topics were in the same paper, and it sounded like 7 that was -- that it read that it would be better 8 to have a focus of your paper. 9 BY MR. GOLOMB: 10 Q Okay. So the -- but the -- but the 11 Gross paper is being sent to the FDA, and Mr. Tisi 12 went through it in great detail this morning, went 13 to the -- to the FDA to defend the industry 14 members against the Citizens Petition, which -- 15 which showed a -- which showed evidence of an 16 association between talc and ovarian cancer, 17 correct? 18 MR. LOCKE: Objection. 19 THE WITNESS: I'm not aware the Gross 20 paper went to the FDA. That was the Huncharek and 21 Muscat document. 22 BY MR. GOLOMB: 23 Q Okay. What was the purpose of the 24 Gross -- 25 A This was -- this was a publication. It</p>

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<p>1 was being published in the peer-reviewed 2 literature. 3 Q By -- by industry members? 4 A It was industry sponsored, yes. 5 Q Right. And so prior to the -- and I'm 6 reading this again: "Prior to submission, 7 however, please delete any reference to the NTP 8 inhalation study conducted in rodents." 9 That's what it says, correct? 10 A Correct. Because I think they were 11 asked to do a paper on ovarian cancer and talc 12 exposure. 13 Q Okay. And so are in vitro or in vivo 14 studies irrelevant to the analysis of the 15 association between talc and ovarian cancer? 16 A I think it's a different topic, and I 17 think -- again, I'm kind of speculating here, but 18 I think this was a paper that was focused on 19 ovarian cancer -- cancer and talc exposure. 20 Q In any event, Mr. Chudkowski, the 21 manager of preclinical evaluations from Johnson & 22 Johnson, was essentially telling Dr. Gross to 23 delete any reference to the NTP inhalation in this 24 letter, correct? 25 A Because it was a very different --</p>	<p>1 A It could mean, or it could mean -- no, 2 here it is. "Review and be prepared to discuss at 3 a meeting." 4 Q At the -- 5 A At an in-person meeting. 6 Q At the January 18th, 1995 meeting of the 7 task force, correct? 8 A Yes. 9 Q And where -- underneath where it says 10 "Requires Action," it says: "The attached draft 11 document," and that is the report from -- is that 12 -- what paper is this referring to? 13 A That's -- I would ask you that. I'm not 14 sure. 15 Q Okay. 16 A I mean, this is the earlier -- 17 Q This is 1994. 18 A Right. 19 Q This is the same time period in which we 20 were talking about Dr. Gross's paper. 21 A Right. 22 MR. LOCKE: Wait. This is 1995. 23 MR. GOLOMB: 19 -- January 11th, 1995. 24 The previous document that we just referred to was 25 1994.</p>
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<p>1 MR. LOCKE: Objection. Lack of 2 foundation, beyond the scope. 3 MS. FRAZIER: Join. 4 THE WITNESS: -- a very different type 5 of study, an animal study and an inhalation study. 6 It's very different. 7 BY MR. GOLOMB: 8 Q Let me show you what's being marked as 9 Exhibit 85. 10 (Exhibit No. 85 was marked for 11 identification.) 12 BY MR. GOLOMB: 13 Q This is a memorandum on CTFA stationery 14 dated January 11th, 1995, to the Talc Interested 15 Party Task Force from Stephen Gettings, director 16 of toxicology at the CTFA. The subject is "The 17 CTFA response to the Citizens Petition." 18 Do you see that? 19 A Yes. 20 Q And this says "Requires Action." Do you 21 see that? 22 A Yes. 23 Q And by require -- in the context of this 24 memo, "Requires Action" means review it and give 25 us back your comments. Correct?</p>	<p>1 MR. LOCKE: May 5th, 1994. 2 MR. GOLOMB: Okay. 3 BY MR. GOLOMB: 4 Q So, in any event, this says: "Subject: 5 CTFA Response to Citizens Petition," correct? 6 A Yes. 7 Q Okay. And as you sit here today, do you 8 know who it was that wrote the response? 9 A No. I would need to see what the 10 attachment is. 11 Q Okay. It says: "The attached draft 12 document has been prepared by J&J in response to 13 the Citizens Petition by the Cancer Prevention 14 Coalition." Correct? 15 A Yes. 16 Q And then attached to that -- 17 MR. LOCKE: Just for the record, this is 18 a document that says at the bottom "1 of 8," and 19 we only have one page. 20 BY MR. GOLOMB: 21 Q Which is the cover page to the 22 memorandum that went to the members of the Talc 23 Interested Party Task Force. 24 Is that consistent with your 25 understanding?</p>

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<p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: That's how I would read</p> <p>3 it.</p> <p>4 BY MR. GOLOMB:</p> <p>5 Q Have you seen this document before?</p> <p>6 A I don't know. I really need to see the</p> <p>7 attachment.</p> <p>8 Q Okay. I'm sorry, but I don't have</p> <p>9 copies of the attachment, but here's the draft.</p> <p>10 A (Peruses document.) Okay.</p> <p>11 MR. LOCKE: Since it's a J&J document,</p> <p>12 I'd like to send it down to their counsel just to</p> <p>13 see.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q It's a -- just to be clear, it's a --</p> <p>16 you've now had an opportunity to see that draft,</p> <p>17 correct?</p> <p>18 A Yes.</p> <p>19 Q And have you seen that before?</p> <p>20 A I'm not sure.</p> <p>21 Q Okay. Did you see the -- the cover</p> <p>22 memorandum before?</p> <p>23 A If I had seen the cover, I would have</p> <p>24 seen the document, so I think I'm saying --</p> <p>25 Q Okay. And so --</p>	<p>1 record. Completing today's videotaped session.</p> <p>2 (Whereupon, the deposition of</p> <p>3 LINDA LORETZ, Ph.D. was adjourned</p> <p>4 at 5:03 p.m.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 A -- probably not, as I recall.</p> <p>2 Q So to be clear, in response to what</p> <p>3 Mr. Locke just said, the draft is a -- and the</p> <p>4 memorandum is a document which was produced by</p> <p>5 J&J, but it's a document on CTFA letterhead,</p> <p>6 correct?</p> <p>7 A Yes.</p> <p>8 Q Okay. But you haven't seen that before?</p> <p>9 MR. LOCKE: Well, wait.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q That you can recall as you sit here.</p> <p>12 MR. LOCKE: This has a C -- this has a</p> <p>13 PCPC document and Bates number on it. So it came</p> <p>14 from PCPC's files. But it says on the cover page,</p> <p>15 "Prepared by J&J." That's what I was referring</p> <p>16 to.</p> <p>17 MR. GOLOMB: Okay. Fair enough.</p> <p>18 I think we're done for the day. That's</p> <p>19 the end of this subject, and we'll pick up</p> <p>20 tomorrow morning.</p> <p>21 MR. LOCKE: Okay.</p> <p>22 MR. GOLOMB: Let's go off the record,</p> <p>23 please.</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 5:03 p.m., October 1st, 2018. We're going off the</p>	<p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER</p> <p>2 The undersigned Certified Shorthand Reporter</p> <p>3 does hereby certify:</p> <p>4 That the foregoing proceeding was taken before</p> <p>5 me at the time and place therein set forth, at</p> <p>6 which time the witness was duly sworn; That the</p> <p>7 testimony of the witness and all objections made</p> <p>8 at the time of the examination were recorded</p> <p>9 stenographically by me and were thereafter</p> <p>10 transcribed, said transcript being a true and</p> <p>11 correct copy of my shorthand notes thereof; That</p> <p>12 the dismantling of the original transcript will</p> <p>13 void the reporter's certificate.</p> <p>14 In witness thereof, I have subscribed my name</p> <p>15 this date: October 2, 2018.</p> <p>16</p> <p>17</p> <p>18 _____</p> <p>19 LESLIE A. TODD, CSR, RPR</p> <p>20 Certificate No. 5129</p> <p>21 (The foregoing certification of</p> <p>22 this transcript does not apply to any</p> <p>23 reproduction of the same by any means,</p> <p>24 unless under the direct control and/or</p> <p>25 supervision of the certifying reporter.)</p>

96 (Pages 756 to 759)

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<p>1 INSTRUCTIONS TO WITNESS</p> <p>2 Please read your deposition over carefully and</p> <p>3 make any necessary corrections. You should state</p> <p>4 the reason in the appropriate space on the errata</p> <p>5 sheet for any corrections that are made.</p> <p>6 After doing so, please sign the errata sheet</p> <p>7 and date it.</p> <p>8 You are signing same subject to the changes</p> <p>9 you have noted on the errata sheet, which will be</p> <p>10 attached to your deposition. It is imperative</p> <p>11 that you return the original errata sheet to the</p> <p>12 deposing attorney within thirty (30) days of</p> <p>13 receipt of the deposition transcript by you. If</p> <p>14 you fail to do so, the deposition transcript may</p> <p>15 be deemed to be accurate and may be used in court.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, _____, do hereby</p> <p>3 certify that I have read the foregoing pages, and</p> <p>4 that the same is a correct transcription of the</p> <p>5 answers given by me to the questions therein</p> <p>6 propounded, except for the corrections or changes</p> <p>7 in form or substance, if any, noted in the</p> <p>8 attached Errata Sheet.</p> <p>9</p> <p>10 _____</p> <p>11 LINDA LORETZ, Ph.D. DATE</p> <p>12</p> <p>13</p> <p>14 Subscribed and sworn to</p> <p>15 before me this</p> <p>16 _____ day of _____, 20____.</p> <p>17 My commission expires: _____</p> <p>18 _____</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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Exhibit 121

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,
SPECIAL TITLE (RULE 3.55)

JOHNSON & JOHNSON TALCUM
POWDER CASES.

JCCP NO. 4872

AFTERNOON SESSION

REPORTER'S DAILY TRANSCRIPT OF PROCEEDINGS

AUGUST 10, 2017

Reporter:

CAROLYN GREGOR, CSR, CM, RDR, CRR
Certificate No. 2351
Court Reporter Pro Tempore

1 CASE NUMBER: JCCP 4872
2 CASE NAME: JOHNSON & JOHNSON
3 TALCUM POWDER CASES
4 LOS ANGELES, CA AUGUST 10, 2017
5 DEPARTMENT 307 HON. MAREN E. NELSON
6 APPEARANCES: (AS HERETOFORE NOTED.)
7 REPORTER: CAROLYN GREGOR, CSR 2351
8 TIME: 1:23 P.M.

9 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
10 COURT OUTSIDE THE PRESENCE OF THE JURY:)

11
12 THE COURT: Back on the record outside the
13 presence of the jury with all trial counsel here.

14 Mr. Robinson?

15 MR. ROBINSON: Yes, your Honor. We're not going
16 to call another live witness, your Honor. We will read
17 from a depo, but we are offering all of our exhibits in
18 evidence, and defense is objecting to some of our
19 exhibits. I think they already came in. I thought they
20 came in with Dr. Godleski. They are his slides. But he
21 put them, you know, into evidence.

22 But I do think we need to have a discussion on
23 these. I got a list about 10 minutes ago from defense
24 counsel of a list of exhibits that they don't want to --
25 that they are opposing, and I think -- I'm okay with them
26 starting the witnesses, your Honor, and I'm willing to
27 tentatively close our case subject to having the Court --
28 first of all, meeting with counsel on the admissibility

1 of our documents, the ones that they are not agreeing to
2 right now.

3 And then we can -- we also are going to be
4 reading in interrogatories, and we have agreed to that as
5 well.

6 THE COURT: And this is also subject to the
7 stipulation that you reached yesterday about the net
8 worth arrangements?

9 MS. ZUKIN: Yes, your Honor.

10 MR. WILLIAMS: Correct. And subject to that
11 agreement, yes, exactly.

12 MR. ROBINSON: So we have the net worth
13 agreement that we have to read in --

14 THE COURT: You don't have to read that in.
15 It's on the record.

16 MR. ROBINSON: It's on the record.

17 And then I told them on these slides I will take
18 out the language on the top of the exhibits. But I do
19 think we need to have -- I don't want to slow down what
20 they are doing. We don't intend to put on any more
21 witnesses, your Honor.

22 I think we could conditionally rest with the
23 understanding that these documents that we're still --
24 and we've been -- apparently this has gone on for a
25 couple days now. We haven't gotten an agreement on the
26 documents, your Honor. So --

27 MR. WILLIAMS: May I just explain briefly our
28 position? May I see that, please?

1 MR. ROBINSON: Yeah, these are them, and there
2 are some others too.

3 MR. WILLIAMS: The question is whether or not
4 documents come in as fully admitted exhibits that the
5 jury gets in the jury room or whether they are merely for
6 identification. And, for example, on the literature, the
7 parties did not agree that they would come in to be
8 admitted but rather for identification purposes.

9 The same with the demonstratives, the
10 photographs, for example, used by Dr. Godleski. Our
11 position is that those were for demonstrative purposes
12 and were not admitted fully.

13 And just for the record, they are Exhibit EE39A,
14 EE39B, EE40A, EE155, and EE39C. And those were all
15 discussed with Dr. Godleski.

16 We believe they can be shown in closing, they
17 can be discussed, but they shouldn't be fully admitted is
18 our position simply because they were photos that were in
19 his report. That's our position on that.

20 And with respect -- and we're happy to permit
21 plaintiff to close, subject to the Court ruling on those
22 things, just so we can get things moving. That's our
23 position on that.

24 With respect to the stipulation, there's one
25 stipulation regarding Exhibit P396 which we'd agreed
26 to --

27 THE COURT: I saw that.

28 MR. WILLIAMS: -- and we have no objection to

1 that being read.

2 And with respect to the interrogatories, we
3 tried to reach a stipulation but couldn't reach agreement
4 because there was language added that was not in the
5 interrogatory responses.

6 So I believe the plan is that Ms. Zukin is going
7 to read three interrogatories, the question and then the
8 answer that is the relevant portion of the answer. And
9 it's Answers to Interrogatories 2, 6, and 17.

10 MS. ZUKIN: Correct.

11 MR. WILLIAMS: And they've asked us whether we
12 would agree that -- to permit the Court to give CACI 209,
13 which is the use of interrogatories --

14 THE COURT: I was just getting out my CACI.

15 MR. WILLIAMS: And we're fine with the use of
16 that.

17 THE COURT: Okay. So we'll just use CACI 209.

18 MS. ZUKIN: We would request that the Court read
19 it before I read the interrogatories.

20 THE COURT: All right.

21 MS. ZUKIN: Thank you.

22 THE COURT: So what we will do when the jury
23 comes back, then, I think we should settle out this issue
24 about the exhibits later so that we can move on to other
25 things. But when the jury comes back, I will instruct
26 them on CACI 209, you'll read the interrogatories and the
27 answers to the interrogatories, plaintiff will
28 conditionally rest with the understanding that the

1 stipulation that you received yesterday may allow you to
2 reopen or not, depending upon how we end up on that.

3 And then how do you want to proceed?

4 MR. WILLIAMS: I would like at that point to
5 make an oral motion, your Honor, once they have closed,
6 conditionally, which will just take me a few moments.

7 THE COURT: Do you want to do that outside the
8 presence of the jury?

9 MR. WILLIAMS: Yes. It will take me three
10 minutes, I think.

11 THE COURT: Okay. He needs to make a record.
12 All right. Let's do that.

13 Do we have the jury back? Can someone go get
14 the jury?

15 MR. WILLIAMS: So I guess we will do those few
16 things and then --

17 THE COURT: And then we will excuse the jury.

18 MR. WILLIAMS: Thank you.

19 THE COURT: And then once your motion is heard,
20 I presume you have witnesses you're ready to call?

21 MR. WILLIAMS: Yes.

22 THE COURT: Okay.

23 MR. ROBINSON: Your Honor, we are going to give
24 you Stipulation Number 1. Mr. Williams and I both signed
25 this.

26 Do you want to read that?

27 MR. WILLIAMS: Sure.

28 MR. ROBINSON: May I approach, your Honor?

1 THE COURT: Sure. Are you going to read that
2 into the record or is it just on the exhibit?

3 MR. ROBINSON: It's on that one exhibit.

4 MR. WILLIAMS: I think it should be read into
5 the record.

6 THE COURT: Do we need to do that in the
7 presence of the jury?

8 MR. WILLIAMS: I don't know that it's necessary.
9 But whatever is the Court's pleasure.

10 MR. ROBINSON: I think I'm okay as long as it
11 gets read into the record.

12 THE COURT: Because the exhibit will go into the
13 jury room and then it will be there.

14 MR. ROBINSON: Yes, your Honor.

15 MR. WILLIAMS: That's right.

16 THE COURT: All right. So the stipulation of
17 counsel is that Exhibit P396 is a fax dated
18 September 30th, 2004, from Mr. Richard Zazenski,
19 Z-A-Z-E-N-S-K-I, of Imerys to Mr. William Ashton of
20 Johnson & Johnson.

21 Defendant Johnson & Johnson stipulates and
22 agrees that it received Exhibit 396 and has kept the
23 document within its company files since the time it was
24 sent.

25 That's the extent of the stipulation; correct?

26 MR. WILLIAMS: Yes, your Honor.

27 MR. ROBINSON: Yes, your Honor.

28 THE COURT: All right. And I'll ask the clerk

1 to file the stipulation.

2 MR. ROBINSON: Then if the Court will read 209.

3 THE COURT: And Ms. Zukin is going to read the
4 interrogatories and the answers to the interrogatories.

5 Do you have a copy of the interrogatories and
6 the answers, Ms. Zukin? Do you have extra copies?

7 MS. ZUKIN: Yes.

8 THE COURT: You might just give those to the
9 court reporter. Sometimes it's handy to have those when
10 somebody is reading something.

11 MS. ZUKIN: May I?

12 THE COURT: Yes.

13 THE REPORTER: Thank you.

14 COURTROOM ATTENDANT: They are coming, your
15 Honor.

16 THE COURT: Okay.

17 (A discussion is held off the record.)

18 THE COURT: And just so I'm keeping up, what's
19 the name of the first witness?

20 MR. WILLIAMS: Dr. Alan Andersen, S-E-N at the
21 end. A-L-A-N.

22 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
23 COURT IN THE PRESENCE OF THE JURY:)

24 THE COURT: All right. Back on the record with
25 all jurors here, both alternates here, all trial counsel
26 here. Let's proceed. Good afternoon, everybody.

27 ALL: Good afternoon.

28 THE COURT: Mr. Robinson, do you have any other

1 witnesses you'd like to call on behalf of the plaintiff?

2 MR. ROBINSON: At this point, your Honor, with
3 the understanding that there are exhibits to be offered
4 after we -- after the -- after we finish court today, the
5 plaintiff will rest conditionally on the Court ruling on
6 those documents.

7 THE COURT: Understood.

8 MR. ROBINSON: And we have to read in also the
9 interrogatory, and the Court's reading in the jury
10 instruction.

11 THE COURT: Right. So let me explain to the
12 jury about this piece of it. So before trial, each party
13 has the right to ask the other party to answer questions,
14 and those are written questions. And the questions are
15 called interrogatories. The answers come out in writing
16 and they are given under oath.

17 So Ms. Zukin is going to read the questions and
18 the answers. You should consider the questions and the
19 answers that are read in court the same as if the
20 questions and answers had been given in court by a
21 witness.

22 Everybody understand that idea?

23 ALL: Yes.

24 THE COURT: Okay. Ms. Zukin.

25 MS. ZUKIN: Thank you.

26 THE COURT: Hold on.

27 (A discussion is held off the record.)

28 THE COURT: Okay. Are you ready to go?

1 MS. ZUKIN: Yes.

2 All right. Good afternoon. I'm going to read
3 the answers by Johnson & Johnson and Johnson & Johnson
4 Consumer Companies, Inc., sometimes referred to in these
5 answers with the acronym JJCC.

6 The first one:

7 Question: State the corporate name of
8 defendant, any name under which defendant does business
9 including state of incorporation, date of incorporation,
10 if applicable, the names and addresses of all officers
11 and other principals of your organization and your
12 registered agent.

13 Answer: In response to the subparts requesting
14 corporate name, trade name, state of incorporation, and
15 date of incorporation, JJCC has been sued under its
16 correct name. JJCC is incorporated in New Jersey and
17 maintains its principal place of business in New Jersey.
18 JJCC was incorporated on March 23rd, 1967.

19 The second question: For each product you have
20 manufactured or sold that contained talc, state -- and
21 this is subpart 3 -- the first and last dates of sale of
22 each product.

23 Answer: In response to subpart 3, Johnson's
24 baby powder debuted in 1893 and remains on the market
25 today. Shower to Shower debuted in the 1960s and it
26 remains on the market today, although it is now
27 manufactured by Valeant Consumer Products.

28 The third question: Please describe the

1 business relationship between Johnson & Johnson and
2 Johnson & Johnson Consumer Companies, Inc., and provide a
3 detailed description of the corporate structure of
4 Johnson & Johnson and specifically how it relates to
5 Johnson & Johnson Consumer Companies, Inc.

6 Answer: JJCC states that it is a wholly owned
7 subsidiary of Johnson & Johnson and has been at all
8 times -- all relevant times. JJCC is incorporated in New
9 Jersey and maintains its principal place of business in
10 New Jersey.

11 Thank you, your Honor. That's it.

12 THE COURT: Thank you.

13 With that read into the record, and subject to
14 the stipulations that we have previously discussed, does
15 the plaintiff rest?

16 MR. ROBINSON: Subject to those stipulations
17 that we discussed previously, your Honor, plaintiffs
18 rest.

19 THE COURT: All right. Thank you.

20 Mr. Williams.

21 MR. WILLIAMS: Thank you, your Honor.

22 The defense calls Dr. Alan Andersen to the
23 stand.

24 THE COURT: All right. Good afternoon, sir. If
25 you would come up here and watch your step. After you
26 get your seat, the clerk will give you the oath.

27 THE CLERK: Sir, do you solemnly state that the
28 testimony you are about to give in the cause now pending

1 before this Court shall be the truth, the whole truth,
2 and nothing but the truth, so help you God?

3 THE WITNESS: I do.

4 THE CLERK: Thank you, sir. You may have a
5 seat.

6 Sir, would you please state and spell your name
7 for the record.

8 THE WITNESS: Alan, A-L-A-N, Andersen,
9 A-N-D-E-R-S-E-N.

10 THE CLERK: Thank you.

11 MR. WILLIAMS: Your Honor, may I approach with a
12 binder?

13 THE COURT: Yes.

14 * DIRECT EXAMINATION *

15 *[1:41 P.M.]*

16 Q BY MR. WILLIAMS: Good afternoon, Dr. Andersen.

17 A Good afternoon.

18 MR. WILLIAMS: Good afternoon, everybody.

19 ALL: Good afternoon.

20 Q BY MR. WILLIAMS: Dr. Andersen, did you
21 previously work at the Food and Drug Administration?

22 A Yes, I did.

23 Q And for how long?

24 A I spent 22 years at FDA.

25 Q Could you tell the members of the jury what
26 years those were.

27 A I started at FDA in 1971, and I worked there
28 until 1993.

1 Q After you worked at the FDA, did you work at an
2 organization called the Cosmetic Ingredient Review?

3 A Yes, I did.

4 Q Is that also known as the CIR?

5 A Yes, it's quicker to say.

6 Q How long did you work at CIR?

7 A I worked at CIR for 20 years.

8 Q What were those years?

9 A From '93, after I had left FDA, until I retired
10 in 2013.

11 Q Dr. Andersen, were you trained as a scientist?

12 A I was.

13 Q Could you describe for the members of the jury
14 briefly your educational background, starting at college.

15 A Okay. Well, I went to Muhlenberg College in
16 Allentown, Pennsylvania. I studied biology, and
17 somewhere along the line I got really super interested in
18 physics, so I kind of parlayed the two. I got my
19 bachelor of science degree in biology from Muhlenberg
20 college and then went on to graduate school.

21 Q What year did you graduate from college?

22 A Oh, now you're asking for memory. I believe it
23 was '66, 1966.

24 Q That's what I have, too.

25 And you received a BS or BA? What was your
26 degree?

27 A BS degree in biology.

28 Q After you graduated from Muhlenberg College,

1 what did you study next and where?

2 A I went further west in Pennsylvania to State
3 College and enrolled in the biophysics program at Penn
4 State.

5 Q what year did you graduate from the biophysics
6 program at Penn State?

7 A well, there were two milestones. One, in 1969,
8 I received my master's of science degree in biophysics,
9 and then in 1971 I finished my Ph.D. work in biophysics.

10 Q And where did you go next?

11 A I got a real job. I went from Penn State to the
12 U.S. Food and Drug Administration.

13 Q what was that year?

14 A 1971.

15 MR. WILLIAMS: Your Honor, can I have a moment?
16 I think I gave counsel my binder accidentally. I just
17 want to make sure I have the right binder now.

18 Thank you. Thank you.

19 Q BY MR. WILLIAMS: We were talking about your
20 Ph.D. program. That was at Penn State as well?

21 A That's correct.

22 Q And you received your Ph.D. in 1972?

23 A The ceremony didn't happen until '72, but
24 everything was finished in '71, and earning a salary
25 seemed like a good idea.

26 Q And the Ph.D. was in what area?

27 A Biophysics.

28 Q Can you describe what biophysics is?

1 A Oh, it's that marriage between biology and
2 physics. But in a simplified form, just about everything
3 that is biological follows the laws of physics as well.
4 So you can predict a lot about what's going to happen in
5 a biological system by knowing what's going to happen on
6 the physics side of it.

7 Just like hitting the brakes on your car is
8 supposed to stop your car. What stops an enzyme when
9 it's moving around in a cell? How does it spin? All of
10 that is governed by the laws of physics, and what we try
11 to do is to use that to better understand the biology.

12 Q In your training did you conduct any research on
13 cell mutations as they applied to cancer?

14 A Yes.

15 Q What did you focus on?

16 A Most of my work in graduate school was on the
17 effects of radiation, particularly ionizing radiation,
18 from radioisotopes. Things that could be incorporated
19 into cells. And that focus kind of shifted when I got to
20 FDA.

21 Q Did you go straight to the FDA after you
22 received your Ph.D.?

23 A I did.

24 Q What was the first position you held there?

25 A I was a researcher in the genetics study section
26 of the Division of Biological Effects of the Bureau of
27 Radiological Health. I can still remember that.

28 Q While you were at the FDA, did you participate

1 in conducting cell studies?

2 A Yes.

3 Q Were you involved in animal studies?

4 A Yes.

5 Q Did you supervise researchers who were doing
6 epidemiological studies?

7 A Yes, I did that too.

8 Q And in what -- how was it -- or in what way did
9 you supervise researchers who were doing epidemiological
10 studies?

11 A Okay. The -- the organization responsible for
12 doing all of the research and testing for
13 radiation-emitting products, X-ray machines, if you will,
14 and all medical products were located within what was
15 called an Office of Science and Technology.

16 And as the director of the Office of Science and
17 Technology, the epidemiology staff had to come to me and
18 convince me the study was well designed, worth doing,
19 before I'd say, "Do it." So it was a supervisory
20 responsibility over what work they were doing.

21 Q And approximately how many epidemiologists did
22 you supervise in that way?

23 A Oh, it usually was a staff of around 10.

24 Q After you were a researcher in the Division of
25 Biological Effects, what was your next position in FDA?

26 A Well, from a researcher, I went to supervisory
27 positions within that same organization. But then
28 finally I was recruited to take over a position at the

1 FDA's Bureau of Medical Devices.

2 Q What were your responsibilities in that role?

3 A I ran -- I was asked to run the standards
4 program. Medical devices are generally classified into a
5 group of regulatory controls, one of which is there
6 should be a standard that this medical device meets in
7 order to assure safety. In fact, that's most medical
8 devices.

9 I was the associate director of standards
10 responsible for all of those medical devices.

11 Q Let me move you to another role you had that may
12 have more direct relation to this case. Did there come a
13 point in time when you became the FDA director of the
14 office of Science and Technology?

15 A Yes.

16 Q Approximately when was that, give or take a few
17 years?

18 A Give or take a few years. '89, 1989, 1990 --
19 '89, I think.

20 Q And what were your responsibilities as the
21 director of the Office of Science and Technology?

22 A All of the engineering and research --
23 engineering testing, research conducted on both medical
24 devices and radiation-emitting products, microwaves,
25 sunlamps, X-ray machines. So it included the full range
26 of radiation products and the full range of medical
27 devices. We didn't do much research on tongue
28 depressors, but computerized tomography and more

1 technically advanced devices, there was a lot of research
2 being done.

3 Q In that role, did you have any authority over
4 how to deploy resources within the FDA?

5 A Yes.

6 Q Were there animal studies or human cell studies
7 or epidemiological studies involved with any of the work
8 that you did in that group?

9 A All of the above.

10 Q What types of specialties, that is --
11 specialists -- excuse me. What type of -- types of
12 specialists did you work with in terms of scientists,
13 physicians? Can you just describe them to the jury?

14 A I think I learned very early on that if you were
15 going to do well as a leader of the effort, you got the
16 best expertise working under you.

17 Toxicology was certainly a big part of the
18 staffing. Engineering because we had the large medical
19 device responsibility. We still maintained the
20 epidemiology research responsibility, so I had
21 epidemiologists on the staff. We had an animal care
22 facility so that we could house and work with the animals
23 in the animal studies.

24 Q Was pharmacology part of the group of
25 specialists underneath you?

26 A Yes, it was.

27 Q Were you also the chair of the FDA Regulatory
28 Review Scientist Peer Review Committee?

1 A Yes, I was.

2 Q Let me ask you a question about that. It's a
3 mouthful. But what is the Regulatory Review Scientist
4 Peer Review Committee all about?

5 A Okay. I described the kinds of things I did at
6 FDA, and that was moving through gradually getting
7 promoted in supervisory positions. And it was more and
8 more management responsibilities kept me going up the
9 ladder.

10 At the same time, there were a lot of FDA
11 scientists who had a benefit to the organization because
12 of their scientific knowledge. And, frankly, it would
13 have been a waste of their effort to, just for a
14 promotion, take their attention away from that science
15 and have to go manage something. Let them do what they
16 are good at. But the system wasn't designed to recognize
17 that. The system of promotions at FDA was designed to
18 get supervisory responsibility, you get a promotion.

19 So I had, in my own work with scientists under
20 me, gotten a few people around the system, just made a
21 strong enough argument so that the office of personnel
22 bought into it.

23 But the problem was hugely widespread at FDA.
24 So it came to a point where the personnel office and the
25 federal office of personnel management came to me and
26 said, look, you've had some success at doing this. Can
27 you make this a system? Define the characteristics of
28 what makes a regulatory scientist really good for FDA and

1 worthy of a promotion without having to take on any
2 supervisory responsibility.

3 And I did that. I developed that scheme and
4 implemented it.

5 Q So the gist of it was to figure out a way that
6 scientists could get promoted without necessarily being
7 supervisors?

8 A That's correct.

9 Q Did you hold any other positions -- and I'd like
10 to move you to the time when you were about to leave the
11 FDA -- what was the last position that you held there?

12 A I was the acting director of the Office of
13 Device Evaluation.

14 Q And what did you do in that role?

15 A Well, device evaluation is a place where all of
16 the industry submissions of scientific data supporting
17 their whiz-bang new medical device is actually safe and
18 effective.

19 So the Office of Device Evaluation was the group
20 that looked at all of those laboratory studies,
21 pre-clinical data, clinical data, submitted by
22 manufacturers to support the safety of medical devices.

23 Q How long did you have that role?

24 A I spent a year as the director of Office of
25 Device Evaluation.

26 Q So that would have been around 1992, just before
27 you left to go to the CIR?

28 A That's correct.

1 Q You went to the CIR or Cosmetic Ingredient
2 Review in 1993?

3 A That's correct.

4 Q How did it come about that you went to the CIR
5 after the FDA?

6 A I was recruited.

7 Q By whom?

8 A The -- an old colleague, an ex-FDA chief
9 counsel, Peter Hutt, reached out and wanted to know if I
10 might be interested in -- in a change of scenery. Peter
11 and Mr. Ed Kavanaugh, who was the president of the
12 Cosmetic Fragrance Association at the time, recruited me
13 to come take over this position.

14 The then director was retiring and they wanted
15 to bring in somebody with FDA regulatory experience to
16 head up this independent review group.

17 Q The CTFA the jury has heard about, the Cosmetic
18 Toiletry, Fragrance Association, is the CIR a government
19 agency?

20 A No, it's not; it's separate.

21 Q Did the FDA participate in the formation of the
22 CTFA?

23 A Yes, they did.

24 Q How was the CIR created?

25 A Well, the creation certainly predated me, but
26 the records are pretty clear. Circa 1976, the industry,
27 the Food and Drug Administration, and the Consumer
28 Federation of America met to talk about how could we do a

1 better documentation of the safety information that we
2 have regarding the ingredients that are used in
3 cosmetics? How would we do that?

4 And they looked at a number of alternatives
5 including, well, the FDA should do it. FDA opined that
6 it didn't have the resources really to do that.

7 Industry said, well, maybe we could support
8 financially creating an independent review group that
9 would look at it.

10 If you can picture the consumer groups at that
11 point saying, well, it has to be sure to be independent
12 because otherwise why would we trust it?

13 So you can see that dynamic going on.

14 In the final analysis, FDA said, if you can
15 create an independent review group to look at these data,
16 that will work. The Consumer Federation agreed with
17 that, and the industry, I think, swallowed hard because
18 they were going to have to pay for it, but the trade
19 association bought in as well, and CIR was created.

20 Q What is the mission of the Cosmetic Ingredient
21 Review?

22 A Well, it's been pretty constant for over 40
23 years now. Review and assess the safety of ingredients
24 used in cosmetics in an open, unbiased, and expert manner
25 and take the results and publish them in the
26 peer-reviewed scientific literature.

27 Q After moving to CIR, did you have a chance to
28 continue working with members of the FDA?

1 A I'm sorry. Say that again?

2 Q Sure. After you moved to the CIR -- and what
3 role did you have at CIR when you went?

4 A Oh, I was from day one the director of the
5 Cosmetic Ingredient Review.

6 Q From the time that you became the director of
7 the CIR, did you continue to work from time to time with
8 people who worked at the FDA in any capacity?

9 A Yes, in several capacities, not the least of
10 which is that, in having bought into this package of
11 creating the Cosmetic Ingredient Review, FDA continued to
12 participate in the process of actually reviewing the
13 safety of cosmetic ingredients by having a liaison
14 representative as part of the process. So there were
15 interactions on a regular basis with the FDA Office of
16 Cosmetics and Colors for that reason.

17 But, more frankly, the interactions with FDA
18 came from my involvement with the Food and Drug
19 Administration Alumni Association, and that brought me in
20 contact on a regular basis -- excuse me -- with folks
21 from all over the FDA. Certainly the Center for Food
22 Safety where cosmetics are -- are dealt with, but every
23 other center at FDA. So my contact level with FDA didn't
24 really decrease when I went to CIR.

25 Q You mentioned something in your last answer, the
26 Center for Food Safety relating to cosmetics. Can you
27 describe that? Because one is food and one is cosmetics.
28 How does that come about?

1 A There are oddities about how organizations are
2 titled all over the place. The overarching regulatory
3 authority that FDA works on is called the Food, Drug, and
4 Cosmetic Act. Cosmetics are in the title of the law.
5 There's no organization at the major breakdown level that
6 has cosmetics in its name. It was determined long ago,
7 and I don't know the genesis of the decision, that
8 cosmetics were most like foods, and that that's where the
9 organizational citing of the cosmetics program would be.
10 It's still called the Office of Cosmetics and Colors
11 because it has responsibility for ensuring the safety of
12 cosmetics and color additives. But it's located in the
13 Center for Food Safety and Applied Nutrition. If you
14 didn't know any better, you would never know that.

15 Q You mentioned a few minutes ago that Mr. Peter
16 Huff had previously been chief counsel at the FDA and
17 then had moved on to the CIR; is that correct?

18 A He had moved on to a position of outside counsel
19 with the CTFA.

20 Q In your professional experience, is it unusual
21 for government employees to leave government and go to
22 work in the private sector or to leave the private sector
23 and to go back to the government? Does that happen?

24 A It does. I haven't gone back the other way yet,
25 but it happens.

26 Q Is it unusual?

27 A No. It's -- it happens.

28 Q What were your responsibilities as director of

1 the CIR?

2 A Oh. Well, as I described to you the mission
3 statement, assess -- review and assess the safety. That
4 means gather the scientific information that are
5 available, seek out any unpublished scientific
6 information that might help figure out whether this is
7 safe or unsafe, and package that information in a way
8 that it can be reviewed by the members of the CIR expert
9 panel.

10 Q Let me ask you -- I'm sorry.

11 A Go ahead.

12 Q Let me ask you some questions about the
13 structure of the CIR in a minute.

14 A Okay.

15 Q But before I get there, in the course of your
16 work at CIR, did you review human cell studies?

17 A Yes.

18 Q Did you review animal studies?

19 A Yes.

20 Q Epidemiology studies?

21 A Yes.

22 Q Did you do that to assess the safety of various
23 substances that are contained in cosmetic products?

24 A Yes. Cosmetic ingredients.

25 Q Approximately how many cosmetic ingredients has
26 the CIR reviewed in its history?

27 A Over 5,000.

28 Q During your time as director, which was from

1 1993 -- and I'm sorry, I didn't get the end date --

2 A 2013.

3 Q From 1993 to 2013, approximately how many
4 cosmetic ingredients did CIR review?

5 A Probably 3,500 of those 5,000. Most of them are
6 under my tenure.

7 Q And after leaving the CIR in 2013, have you
8 continued to work?

9 A Yes, I have, sparingly.

10 Q Would you call yourself semi-retired?

11 A I think I'm fully retired with dipping my foot
12 in occasionally.

13 Q How often -- strike that.

14 what types of consulting do you do?

15 A I aligned with a consulting firm in Virginia
16 that provides the administrative support so that I don't
17 have to handle all of the paperwork part of it.

18 But the things that I've done have been working
19 on, advising a developing cosmetic company on how to
20 construct their labeling. I've done work through the
21 consulting company on a lawsuit concerned about radiation
22 leakage from electron microscopes, harkening back to my
23 radiation protection days. And I've gotten involved in
24 this litigation.

25 Q And you're referring to this talc litigation;
26 correct?

27 A That's correct.

28 Q So you've been retired since 2013. So

1 approximately going on four years now; is that right?

2 A Boy, it is four, yes.

3 Q And those -- you just listed the different
4 engagements that you had in that time?

5 A Yes. It wasn't my plan to do a lot. But it's
6 nice to keep your hand in.

7 Q Did Johnson & Johnson retain your services in
8 this case to discuss, among other things, the policies
9 and procedures and practices at the Cosmetic Ingredient
10 Review?

11 A Yes.

12 Q How much is Johnson & Johnson being charged for
13 your time?

14 A \$695 an hour.

15 Q Was that always the rate?

16 A No, it's -- last year it was 650. I'm not sure
17 what it was the -- well, let's see. This is 2017. And I
18 only started in 2016. So it was 650 in 2016, 695 this
19 year.

20 Q Have you been asked to provide an opinion
21 regarding an assessment as to whether talc is safe?

22 A Yes.

23 Q Have you been asked to do that to a reasonable
24 degree of medical certainty -- or scientific certainty?

25 A Well, scientific certainty.

26 Q Excuse me. I misspoke. Scientific certainty.

27 A Yes.

28 Q Have you been asked to give an opinion -- or to

1 describe, rather, the CIR review process that it
2 undertook regarding talc?

3 A Yes, that's -- that's the how-it-was-done part.

4 Q I'd like to shift gears and talk about the
5 process that CIR uses to assess or review ingredients in
6 a general way. And I assume that that general way that
7 it assesses ingredients would apply to talc as well; is
8 that right?

9 A Yes, there aren't two ways of doing it. There's
10 a way we do it, and that's how we do it.

11 Q Did you help to prepare a demonstrative to just
12 show the overall structure of the CIR?

13 A Yes.

14 MR. WILLIAMS: Your Honor, we've provided these
15 to counsel. This would be slide 2.

16 THE COURT: Counsel, have you seen the slide?

17 MR. SMITH: I don't have a problem with slide 2,
18 your Honor.

19 THE COURT: All right. Thank you.

20 MR. WILLIAMS: If we could publish that,
21 Mr. Bales.

22 Q BY MR. WILLIAMS: Over on the left, Doctor, it
23 talks about the steering committee. And it says "seven
24 members."

25 Could you describe for the members of the jury
26 whether CIR has rules that define the membership of the
27 steering committee, the seven-member committee?

28 A Yes. It's spelled out in very great detail in

1 the CIR procedures by which we operate.

2 Q when were those procedures put in place?

3 A Oh, they were done in 1976.

4 Q what is the makeup -- or is there any particular
5 makeup of the seven members of the steering committee?

6 A Yes, there is. It's -- most of the positions
7 are organizational. So, for example, the American
8 Academy of Dermatology, the physicians group in this
9 country that comprises dermatologists, appoints a member
10 to the steering committee. The Society of Toxicology,
11 one of the U.S -- well, international, really -- groups
12 of professional toxicologists, the Society of Toxicology
13 appoints a member to the steering committee.

14 The Consumer Federation of America -- I didn't
15 really describe them earlier, but the Consumer Federation
16 is an organization of consumer activist organizations
17 from around the country, public interest research groups
18 from all over, that band together to -- in an effort to
19 assure consumer interests are protected. The Consumer
20 Federation appoints a member to the steering committee.

21 Q You covered three positions. Is there a fourth
22 that is always a member of the committee?

23 A well, there's the -- the chair of the CIR expert
24 panel was made a part of the CIR steering committee.

25 Q So you've now listed four different positions.
26 Are there -- of the remaining three members, who sits on
27 the steering committee as the remaining three members?

28 A Okay. The other three members, it includes the

1 president now of the Personal Care Products Council,
2 because it changed its name from CTFA. It includes the
3 vice president for science at the Personal Care Products
4 Council, and it includes -- I think it's always been an
5 industry person, but the companies change -- an industry
6 scientist who chairs the trade association's CIR Science
7 and Support Committee.

8 Q So there are four -- excuse me, strike that --
9 there are three members from industry, four members from
10 the scientific community?

11 A That's correct.

12 Q Is that intentional?

13 A Very much so.

14 Q Why?

15 A The decisions made about any changes in policy
16 direction, decisions made about who should be appointed
17 to the CIR expert panel, if there's a vacancy, those
18 should be made by a group that is mostly not industry.

19 Q How are the CIR activities funded?

20 A The Personal Care Products Council pays the
21 bills.

22 Q Do they fund the salaries of the people who are
23 the full-time employees of the CIR?

24 A Yes, they pay the salaries.

25 Q How about the members of the steering committee?
26 Are they paid?

27 A You know, oddly enough, no. All the members of
28 the steering committee in their work, they've always done

1 it just because it's a good thing to do.

2 Q You mentioned that one of the members of the
3 steering committee is also the chairperson of the expert
4 panel.

5 A That's correct.

6 Q Could you describe for the members of the jury
7 the membership of the expert panel and how that works.

8 A Okay. well, the panel of experts -- expert
9 panel -- is a group of nine individuals with medical and
10 scientific backgrounds who are charged with looking at
11 the -- the data that are available on each cosmetic
12 ingredient that's being reviewed. And they do that at
13 meetings several times a year, and then they come back
14 and repeat it again because there's a lot of cosmetic
15 ingredients.

16 Q How long do the members of the expert panel
17 serve in that capacity?

18 A The CIR procedures call for a six-year
19 appointment, and the procedures say that's renewable
20 once. And then it says, after that, we'll look and see.

21 Q Are the members of the expert panel that works
22 for -- strike that.

23 Are the members of the expert panel, those nine
24 people, are they paid?

25 A Yes, they are paid.

26 Q What are they paid?

27 A They're paid an hourly rate for the work that
28 they do reviewing material in preparation for each panel

1 meeting. And that's significant because it's, you know,
2 not like somebody handing me this binder. It's boxes
3 full of scientific material that they are getting to look
4 at in preparation for an upcoming meeting.

5 So they spend their time with that information,
6 reviewing it. And they keep track of their hours. And
7 they submit a time sheet to the CIR afterwards. For each
8 of the days that they spend at the meeting, they also get
9 paid an hourly rate.

10 Q The CIR and the PCPC offices at the time that
11 you were last working at the CIR, were they in the same
12 office suite or building, or how was the setup?

13 A Well, it changed while I was there. When I left
14 in 2013, the CIR suite was on a different floor -- in the
15 same building, but on a different floor -- from the trade
16 association.

17 Q Did that fact, the fact that they were in the
18 same building on different floors, affect the
19 independence of the CIR in reviewing?

20 A No. The CIR procedures specifically flagged the
21 issue of the CIR program is to be an independent program.

22 So I don't know how much of a measure it is of
23 independence, but whenever someone from the trade
24 association visited the CIR offices, they had to sign in
25 and state the purpose of their visit, just like they were
26 any other non-CIR individual. So it was a way of keeping
27 track of what was happening and help ensure the
28 independence.

1 Q Other than the sign-in procedures that you just
2 described, did the CIR take any other steps to ensure
3 that the CIR acts independently of industry with respect
4 to conflicts of interest and the like?

5 A Well, conflicts of interest is -- is a piece
6 that was, again, in the procedures very specifically
7 applied to the members of the expert panel.

8 Panel members are required to not have any
9 conflicts of interest. They can't consult for cosmetic
10 companies. They are to have no financial interest in
11 that group of products that are being regulated -- wrong
12 word. I keep putting on my FDA hat -- that are being
13 evaluated by the Cosmetic Ingredient Review program. And
14 those -- that information is provided.

15 Thankfully, we stayed away from forms, but panel
16 members are to tell me about what their interests are and
17 certify that they don't do any work for the cosmetics
18 industry.

19 Q Let's talk about the expert panel, the
20 nine-person panel. What does the expert panel do?

21 A Oh, they review that ton of material at each of
22 their meetings and assess what they think it means.

23 Q Are there any members of industry on the
24 nine-person expert panel?

25 A No, there aren't.

26 Q How is the expert panel -- how are the members
27 chosen to be on the expert panel for the CIR?

28 A Well, at the beginning, and then any time a

1 vacancy occurs, there's an open public process by which
2 nominations are sought. The word goes out to scientific
3 societies, medical groups, certainly consumer interest
4 groups, "Here's what we're looking for in terms of expert
5 scientists and physicians. Can you please nominate
6 somebody whom you think would be good to serve in this
7 capacity."

8 And those nominations are collected. And it's
9 the steering committee that makes the decision on who is
10 to be selected.

11 Q Did your expert report list the nine members of
12 the expert panel who were sitting in the nominee expert
13 panel at the time that talc was reviewed by the CIR? Did
14 you list those names in your report?

15 A In my expert report? No, I don't think I did,
16 actually.

17 Q Can you recite the names of those folks?

18 A Oh, yeah.

19 Q Did you help us to prepare a slide with the
20 names of the individuals and their photographs?

21 A Yes.

22 MR. WILLIAMS: Your Honor, permission to publish
23 slide 3 from the package that we gave counsel.

24 THE COURT: Mr. Smith?

25 MR. SMITH: No objection, your Honor.

26 THE COURT: Thank you.

27 Q BY MR. WILLIAMS: If you would, Dr. Andersen,
28 start with the first person listed here, which is

1 Dr. Wilma Bergfeld, B-E-R-G-F-E-L-D. And if you would,
2 for the members of the jury, describe the professional
3 background, starting with Dr. Bergfeld.

4 A Okay. I can do that.

5 Wilma Bergfeld is a dermatologist. She's also a
6 dermatopathologist. She runs the dermatopathology
7 program at the Cleveland Clinic. Wilma is a practicing
8 dermatologist, the first woman ever to be the president
9 of the American Academy of Dermatology. She still works
10 two times a week in the pathology lab looking at slides,
11 evaluating and feeding back to the physicians, was this a
12 cancer, not a cancer, benign cancer, malignant cancer.
13 Looking at tissue samples and reporting back is a big
14 part of her responsibility at the Cleveland Clinic.

15 Q Let me stop you there. Was Dr. Bergfeld the
16 chairperson of this panel during the time that talc was
17 reviewed?

18 A Yes, she was.

19 Q And therefore, was she the person who also sat
20 on the steering committee at the CIR as well?

21 A That's correct.

22 Q Could we move now to James Marks, Jr.

23 A Jim Marks is also a dermatologist. At the time
24 that the talc safety assessment was done, Jim was the
25 chair of dermatology at the Penn State Medical School in
26 Hershey, Pennsylvania. Jim's expertise is primarily in
27 contact dermatitis, how the skin reacts to anything that
28 contacts it.

1 He also is a major force behind the North
2 American Contact Dermatitis Group, which is a consortium
3 of high-level physicians across the country that run
4 essentially a monitoring service of, whoa, what's new in
5 terms of what we're seeing in the population as far as
6 upcoming adverse effects on the skin? So it's a
7 monitoring effort. And Jim was very good about keeping
8 all of us in touch with what the medical community
9 actually knows currently.

10 Q Let's move to Donald Belsito, M.D., at Columbia
11 University Medical Center.

12 A Okay. Don is also a dermatologist. His
13 specialty is in immune-related diseases. Psoriasis would
14 be an example. And his expertise in terms of both the --
15 looking at human disease that extends beyond just looking
16 at the skin, as some of these diseases go further than
17 just the surface.

18 Q Next is Daniel Liebler, L-I-E-B-L-E-R, Ph.D.,
19 from Vanderbilt University School of Medicine.

20 A Okay, Dan is the director of the Ayers Precancer
21 Detection and Treatment Unit that -- at Vanderbilt's
22 School of Medicine. He's also a college -- professor of
23 pharmacology, biochemistry, and biomedical informatics.
24 His research relates to what are the mechanisms by which
25 things are carcinogenic.

26 Q Next is Ronald Hill, Ph.D., from the College of
27 Pharmacy at the University of Louisiana at Monroe. Could
28 you just describe --

1 A Okay. Ron is a medicinal chemist. And that was
2 important to bring onto the panel because CIR had found
3 itself dealing with a large number of cosmetic
4 ingredients that were derived from botanical sources, and
5 that -- those ingredients are almost always mixtures, and
6 it wasn't always clear what was in them.

7 Ron Hill's background in medicinal chemistry was
8 focused on: Okay, how do I deal with these mixtures?
9 what happens to them when they get in the body? what
10 kind of transformations do they undergo? what kind of
11 transformations do they cause? And that turned out to be
12 a rather important addition to the panel's expertise.
13 It's certainly chemistry but a focus on medicinal
14 chemistry.

15 Q Next is Curtis Klaassen, K-L-A-A-S-S-E-N, Ph.D,
16 from the School of Medicine at the University of Kansas.

17 A Okay. I mean, Curt is overall a toxicologist.
18 I mean, his subspecialties include pharmacokinetics, a
19 question of what does happen and how is it processed once
20 it gets in the body? But, overall, he's just well
21 recognized as a leader in the toxicology community.

22 You've heard it said that, you know, when you
23 describe somebody's expertise, he wrote the book. Curt
24 wrote the book -- probably the most widely used
25 toxicology textbook is Curt's textbook.

26 Q Next is Paul Snyder, DVM. What does "DVM" stand
27 for?

28 A Doctor of Veterinary Medicine.

1 Q And he is a Ph.D. as well?

2 A That's correct.

3 Q At the Experimental Pathology Laboratories. Why
4 a veterinarian on the board?

5 A Well, all of that bulk of data that the panel
6 receives includes a bunch of animal studies. And having
7 somebody -- and certainly Paul is a veterinarian but his
8 particular specialty is veterinary pathology. So his
9 expertise allows him to look at those studies and make
10 evaluations of what -- of how it was done, what the
11 findings are, and what the interpretations legitimately
12 should be. His Ph.D. was in immunology, which adds a
13 little bit more of that expertise to the CIR expert
14 panel.

15 Q Two more. One, Dr. Thomas Slaga -- is that how
16 you pronounce that? -- from the University of Texas.

17 A Yes.

18 Q Describe his background.

19 A We used to call Tom "Mr. Carcinogenesis." Tom
20 has been involved in studying mechanisms of
21 carcinogenesis for some 50 years now. He's headed cancer
22 treatment centers. I don't know what the acronym stands
23 for -- AMC Cancer Research Center in Colorado. For a
24 while, he headed the cancer treatment center at the
25 University of Texas Health Science Center in San Antonio
26 until he backed off to have more time doing his research.

27 But his background expertise is in the
28 mechanisms by which cancer is caused. He started the

1 journal Molecular Carcinogenesis so that there was a way
2 to get more of these studies published in the scientific
3 literature.

4 Q And finally, Ronald Shank, S-H-A-N-K, Ph.D.,
5 he's professor emeritus from the Department of Medicine
6 from UC Irvine. Can you describe his background.

7 A Okay. Ron, about the time when we were working
8 on talc, moved to his emeritus status. He had been the
9 director of the environmental health sciences program at
10 the department of medicine at UC Irvine. He created that
11 program. I'm not sure when it started, but he was the
12 guy that started it as an overarching program to train
13 scientists in how to evaluate any health concerns
14 relating to environmental pollution. So it included how
15 do you look at human studies? How do you look at cell
16 studies?

17 His own particular research, like others on the
18 panel, was on actually the mechanisms of carcinogenesis.

19 Q Great. Thank you. So what are the
20 classifications that the CIR uses to reflect its
21 assessment of the safety of ingredients contained in
22 cosmetics? What are the different categories or
23 classifications that exist?

24 A Okay. Well, the -- again, it's all spelled out
25 in --

26 Q And let me stop you again. Did you prepare a
27 slide that lists those categories?

28 A I think we have one, yes.

1 MR. WILLIAMS: Your Honor, permission to publish
2 slide 4.

3 MR. SMITH: No objection.

4 THE COURT: Thank you.

5 Q BY MR. WILLIAMS: If you would, Dr. Andersen,
6 just describe what each of these categories mean.

7 A Okay. Well, safe means that, after looking at
8 all of the available information, the panel determined
9 that it was perfectly okay to use this ingredient in
10 cosmetics. Almost always -- and safe is a one-word way
11 of saying it -- but almost always the panel says safe in
12 the present practices of use and concentration, because
13 the package that they're presented provides a background
14 on how this ingredient is actually used in cosmetics. Is
15 it used in creams and lotions? Is it used in sprays?
16 How is it used and at what concentrations?

17 So they have that information at hand and have
18 increasingly over the years -- I think I pushed them in
19 that direction -- have added that statement of "safe" and
20 look at the report to see how it's used and at what
21 levels it's used. So that's the safe category.

22 Q Dr. Andersen, are you familiar with the -- you
23 mentioned that there are approximately 5,000 ingredients
24 that have been reviewed in the history of the CIR.

25 A Yes.

26 Q Are you familiar with the data that would
27 reflect how many or what percentage of the ingredients
28 that have been reviewed that have fallen into these

1 different categories?

2 A Yes, I am.

3 Q How are you familiar with that?

4 A I get updates from the CIR staff on what the
5 numbers look like.

6 Q With respect to the category you just described,
7 the safe category, approximately what percentage of the
8 ingredients that have been reviewed have fallen into that
9 category?

10 A 42 percent.

11 Q Could you describe the next category, "Safe with
12 qualifications."

13 A Okay. "Safe with qualifications," well, it is
14 pretty much what that says. This ingredient, the panel
15 found, can be used safely in cosmetics if -- and then
16 comes the "if." Many of those ifs are, it's okay to use
17 in a product that's going to be rinsed off, but don't use
18 it in a product that's a leave-on product.

19 Some of those qualifications are, don't use it
20 above a given concentration. So put a limit on the
21 concentration of the ingredient that can be used.

22 There are qualifications that talk about
23 ensuring that the consumer is alerted to a particular
24 issue. So you've actually included in -- well, I don't
25 know -- I guess in a couple now -- specific language that
26 said that the qualification should include providing
27 warning information to a user.

28 Q What percentage of the ingredients that have

1 been reviewed by the CIR have fallen into the "safe with
2 qualifications" category?

3 A It's virtually -- you know, 56 1/2 percent.
4 Almost -- it's almost all of the rest.

5 Q And let's talk about the "unsafe" category.
6 Approximately how many ingredients have been identified
7 as unsafe by the CIR based on its review in its history?

8 A I think CIR's -- I don't think anything new that
9 I can recall. So we're up to 13 ingredients that have
10 been identified as unsafe for use in cosmetics. It's
11 about 1 percent. Let's see, 5,000 -- I can't do the math
12 in my head.

13 Q Now, 5,000 products reviewed, only 13
14 ingredients found to be unsafe. To what do you attribute
15 that relatively small number?

16 A Oh, I -- I don't see it as a small number.

17 Q Explain.

18 A The expectation is that ingredients used in
19 cosmetics are safe. That's kind of the mindset that you
20 ought to have going into this. And I feel pretty pleased
21 that we were able to identify 13 ingredients that said
22 get them the heck out of cosmetics. That's an important
23 accomplishment from my standpoint.

24 Q The final category is "insufficient data." What
25 does that mean for purposes of the review panel?

26 A It -- it means that, as much information as we
27 gathered and try as we would, it just isn't enough
28 information on which to make a determination. And we

1 can't say it's unsafe; we can't say it's safe. We can't
2 even put a qualification on it. We just don't know
3 enough. And --

4 Q Let me stop you there. If something is put into
5 the insufficient data category, can it go there forever,
6 or is there any time limit by which something has to be
7 done about it to take it out of the insufficient data
8 category?

9 A Yes. I think -- I mean, insufficient data is
10 kind of -- you're left hanging. So what happens next?

11 The CIR procedures specify that a two-year clock
12 starts. And within that time frame, any interested
13 party -- I mean, it talks about any interested party.
14 The message is, "Dear industry, provide us the data.
15 It's your ingredient; give us the data."

16 And if, at the end of those two years, the data
17 are not provided, it moves into a category that says
18 "should not be used in cosmetics."

19 Q And let me stop you there. In the insufficient
20 data category, I take it that's about 1 percent as well?

21 A Yeah, it's the remaining.

22 Q Okay. What category was talc placed in after
23 the CIR conducted its review of talc?

24 A Talc is in the safe category.

25 Q During the -- and that was on the basis of --
26 what -- how long -- from the time talc was first reviewed
27 or put up for review to the time that a CIR report was
28 prepared, how much time elapsed?

1 A In your question were you referring to
2 preparation of an initial report or a final report?

3 Q Well, let me be more specific.

4 I'm going to ask you in a minute how it came to
5 be that talc was reviewed. But before we get there, from
6 the point in time where talc was put up for review to the
7 point in time when a final report was done by the CIR on
8 talc, how much time elapsed approximately?

9 A About a year and a half.

10 Q With respect to the safe evaluation for talc
11 that ultimately occurred, was there -- was this a close
12 call based upon your years of experience?

13 A That's an interesting question. It sure didn't
14 seem like it. The panel was -- was very clear in their
15 evaluation of the data and that it supported the safe in
16 the present practices of use and concentration
17 conclusion.

18 Q Let me ask you a question about those
19 ingredients that have been rated or categorized over the
20 years in categories other than the safe category, so safe
21 with qualifications or unsafe.

22 In those situations where an ingredient was
23 listed as either safe with qualifications or unsafe, were
24 there industry representatives making comments that they
25 believed the ingredients should be listed as safe?

26 A It did not occur. I mean, self-interest is a
27 powerful thing, and folks would make comments. But the
28 focus of the CIR expert panel discussions is -- is just

1 so uniformly on the science that the opinion issue
2 doesn't really come to play.

3 Q For each of the products that have been
4 categorized as unsafe -- strike that.

5 For each of the ingredients -- excuse me -- that
6 have been categorized as unsafe or as safe with a
7 qualification, I take it there was an industry behind
8 that ingredient and product that was seeking a safe
9 evaluation? would that be accurate?

10 A My perception of the industry participation over
11 my 20 years is just slightly different spin than you are
12 phrasing it.

13 Q Please go ahead.

14 A The industry input is best categorized as
15 wanting to get to the right answer. I mean, yes, there
16 was self-interest that was expressed at times, saying "I
17 want this to be safe." But, by far, the tenor of the
18 input over my 20 years there was, let's get to the right
19 answer.

20 Q Let's move into the review of talc. Did the CIR
21 specifically review and consider whether talcum powder is
22 safe for use in the perineal area by women?

23 A Yes, that was part of the safety assessment.

24 Q Does the CIR have a set procedure for reviewing
25 the safety of an ingredient?

26 A Yes, we do.

27 Q Did the CIR apply those rules and procedures to
28 its review of talc?

1 A Yes.

2 Q How is it that talc came to be selected for
3 review, and when did that occur?

4 A Okay. The CIR expert panel is assigned the
5 responsibility of establishing the priorities for review.
6 Nobody else. It's -- the panel says, "This is going to
7 be our top priority for review."

8 They use a number of factors in making that
9 determination, but right at the top of the list is how
10 frequently is this ingredient used in cosmetics. And the
11 panel has that at the top of the list because that's
12 likely an indicator of how many people are going to be
13 exposed. So that's important.

14 Q Was the -- was the CIR provided a list of the
15 approximate number of products that contain talc in
16 making the assessment that you just described?

17 A Yes. The U.S. Food and Drug Administration
18 maintains a Voluntary Cosmetic Registration Program,
19 VCRP. And companies submit information on their use of
20 ingredients to FDA, and FDA captures all of that
21 information. And each time CIR does a safety assessment,
22 FDA provides that information to CIR on the -- on the
23 types of products and the -- the frequency in that
24 product category.

25 Q Approximately how many products contained talc
26 at the time a decision was made to review talc?

27 A I couldn't give you that number unless I looked
28 at the table.

1 Q Okay. Let me see if I can refresh your memory.
2 would looking at the CIR report itself help to refresh
3 your memory?

4 A Okay. The safety assessment.

5 Q In that notebook in front of you, there's an
6 exhibit -- it should be marked as Exhibit L384.

7 A Got it. Okay.

8 Q Do you have that there?

9 A I do.

10 Q And if you would --

11 And don't publish this, Mr. Bales. This is just
12 to refresh his memory.

13 If you turn to page 5 of L384, it should have it
14 there.

15 A Yeah, I've got it. It's the total number of
16 uses reported was 3,469.

17 Q Was that 3,469 number of products containing
18 talc the primary factor that pushed the CIR to review the
19 safety of talc?

20 A Yes, it was.

21 Q Approximately when was it that CIR decided it
22 would review talc?

23 A CIR had initially put it as a priority in 2009.
24 And then, unfortunately, I lost a staff person who was
25 working on it, so it went into a bit of a limbo. And
26 then I assigned it to a new staff person who began work
27 in late 2011. And she worked on it continuously until
28 its completion.

1 Q who was that staff member?

2 A Monice Fiume.

3 Q would you spell that, please?

4 A M-O-N-I-C-E, F-I-U-M-E.

5 Q what is Ms. or Dr. Fiume's --

6 A Ms.

7 Q -- Ms. Fiume's educational background?

8 A Bachelor of science degree and a master's
9 degree. She had worked doing animal testing and research
10 before she came to CIR.

11 Q Did the decision to review talc by the CIR
12 relate to numbers of claims, publicity, anything of that
13 kind relating to talc?

14 A No, it didn't.

15 Q Had talc ever been reviewed before by the CIR?

16 A No.

17 Q Have there been occasions where a request has
18 been made to the CIR to have a particular ingredient
19 reviewed?

20 A well, yes, there have been.

21 Q Can you give us an example?

22 A Probably the most requests for CIR to
23 immediately start something and do a safety assessment
24 have come from FDA. FDA didn't ask us to review talc,
25 but FDA has asked to review ingredients of --
26 formaldehyde and methylene glycol is used in
27 hair-straightening products. FDA asked the panel to
28 review alpha hydroxy acids that are used in skin lotions

1 and are supposedly to help smooth out your skin.

2 I would have to go back and see if I can come up
3 with others -- they were --

4 Q That's all right.

5 A It's not infrequent, but it's not frequent
6 either.

7 Q Were there any requests by the FDA or any other
8 organization for a review of talc by the CIR?

9 A No.

10 Q Had the CIR ever received requests that a review
11 of talc should be accelerated because of any safety
12 concern for talc?

13 A No.

14 Q What's the next step after naming an ingredient
15 to be put on the priority list for review -- what is the
16 next step that has to happen?

17 A Once it's assigned as a priority ingredient, you
18 begin to gather the data.

19 Q And how were the scientific data compiled in
20 this case?

21 A Searching through as many scientific search
22 engines as you can use to find what information has been
23 published.

24 We had the advantage in this circumstance of
25 also involving Dr. Ivan Boyer who was a toxicologist on
26 the CIR staff. Ivan and Monice worked side by side to --
27 to really harvest the information from whatever source we
28 could find.

1 Q Is there some formal name that's given to the
2 group of materials that were compiled in this case by
3 Dr. Boyer and Ms. Fiume?

4 A Yes, CIR calls it a scientific literature
5 review.

6 Q And what is that?

7 A Well, it's that collection and description -- I
8 mean, it's a bibliography at the end which says here's
9 what we looked at. But in the text it describes what
10 each of these studies was, what it did, and what it
11 found. No value judgments; it just presents what the
12 study was and what the findings were.

13 And it breaks those out into some logical
14 organization. Cell studies are bunched with cell
15 studies, animal studies with animal studies, epidemiology
16 is with epidemiology. And that literature review is --
17 we call it published. I mean, it's put on the website,
18 and the notice is, this is available -- freely available
19 to anybody that wants it for public comment. There's a
20 60-day public comment period. So any interested party
21 can review what we came up with for the scientific
22 literature.

23 Q Let me stop you there. I'm sorry to cut you
24 off. Let me just ask a question.

25 Once the scientific literature review package is
26 pulled together, can panel members, members of the review
27 committee -- the nine folks that you listed earlier --
28 can they ask for more information?

1 A They haven't seen it yet. So at that stage,
2 they wouldn't be asking for more information. Their shot
3 comes at the next step.

4 Q You indicated that the scientific literature
5 review package, that compilation, you said that it's made
6 public. Can outsiders -- industry, academia, consumer
7 groups -- can others weigh in on the data selection?

8 A Everybody.

9 Q Did that happen in the case of talc?

10 A I mean, not in a substantial way. We did get
11 input but from a very narrow sector.

12 Q Was there industry input on the -- the universe
13 of literature that was compiled?

14 A I think we received from one source a
15 bibliography of here's what we found. You know, here you
16 are, CIR.

17 Q Are those submissions made public?

18 A Yes.

19 Q Was the entire scientific literature review data
20 made public?

21 A Yes. It's the hallmark of the CIR process that
22 everything is going to be made public.

23 Q And when you say "everything," you're referring
24 in this case to the specific literature review that is
25 the universe of materials?

26 A The literature review. Since the comments we
27 receive aren't published anyplace, we make all the
28 comments public. So it's a process that celebrates the

1 openness.

2 Q After that 60-day comment period that you
3 referenced, what happens next?

4 A All of the -- any input that CIR received is
5 incorporated with the original scientific literature
6 review, and what we call a draft report is prepared.
7 It's still really just that presentation of the available
8 science, but it now has added to it anything that -- that
9 we've received.

10 And that draft report, two things happen. One
11 is that it's published on the website. So, again, any
12 interested party can look at it. It's part of the agenda
13 for an upcoming CIR expert panel meeting.

14 And then it goes both to any interested party,
15 because it's on the website, and, in particular, at this
16 point in time, we had just started doing --
17 electronically providing material to the panel. So they
18 were getting it all at the same time.

19 Q Let me stop you there.

20 Did the PCPC provide information to -- that was
21 included in the scientific literature review package?

22 A Not in front of preparing the scientific
23 literature review, but in response to the scientific
24 literature review, we received input from the trade
25 association.

26 Q Do you remember any specific type of data that
27 they provided, the PCPC?

28 A Oh, to be honest, most of it reads like typos.

1 But, you know, you'd get a comment that said that you had
2 a guinea pig study that you included in the
3 single-dose-exposure part of your report, but it also
4 looked for cancer, so please also mention it in the
5 cancer section.

6 That's good input. It helps make sure that, as
7 you read the report, nothing gets mixed. So that it's
8 either typos or highly technical comments on the science.

9 Q Do you recall when it was that the scientific
10 literature review was made public?

11 A August 2012, I think. The day in August, I
12 don't remember.

13 Q And you mentioned already the 60-day comment
14 period. Did there come a point in time when the draft
15 report was prepared?

16 A Yes.

17 Q When was that?

18 A That was November of 2012.

19 Q Who prepared the draft report?

20 A Monice Fiume, Ivan Boyer, and Al Andersen.

21 Q That's you; right?

22 A Yep.

23 Q Were there comments received in response to the
24 draft report?

25 A Yes, I think we did get some comments.

26 Q And I got ahead of myself. Was the draft report
27 made public?

28 A Yes, it was put on the CIR website as a PDF.

1 And anybody that wanted to download it could download it
2 and look at it.

3 Q When was the first meeting of the actual expert
4 review panel after that draft report was prepared?

5 A December of 2012.

6 MR. WILLIAMS: Your Honor, I was about to go
7 into that meeting. Would this be an appropriate time?

8 THE COURT: It would. Let's take a 10-minute
9 recess, stand up and stretch. Leave your notes here and
10 please take a short recess with the usual admonitions in
11 mind.

12 *[2:59]*

13 (Jurors excused.)

14 (Brief recess taken.)

15 THE COURT: All right. Back on the record with
16 all jurors here, the witness on the stand.

17 Go ahead, Mr. Williams.

18 MR. WILLIAMS: Thank you, your honor.

19 *[3:14]*

20 Q BY MR. WILLIAMS: Dr. Andersen, just before the
21 break we had moved through time and had just gotten to
22 the point where the first expert panel meeting relating
23 to talc occurred.

24 Do you have that time frame in mind?

25 A Yes, I do.

26 Q When was it that the first expert panel meeting
27 took place?

28 A December of 2012.

1 Q How often does the expert panel meet each year?

2 A The panel meets four times a year.

3 Q And at each one of those meetings, over what
4 period of time does it occur? One day? Two days? Three
5 days?

6 A Each meeting is a two-day meeting.

7 Q So there are eight days in a given year that the
8 entire expert panel meets together?

9 A That's correct.

10 Q Does the expert panel consider multiple
11 ingredients at a time?

12 A Yes.

13 Q Are the expert panel meetings open to the
14 public?

15 A They are.

16 Q Are the meetings recorded?

17 A They are.

18 Q Could you explain generally how an expert panel
19 meeting is run.

20 A Yes, I can.

21 Q Please do.

22 A On the first day of a CIR expert panel meeting,
23 something I instituted, I break the expert panel into two
24 teams, and they each separately review all of the
25 material. Scientists can be as competitive as anybody
26 else. And it's an approach that really pushes each of
27 these two review teams to do their best job they can at
28 assessing the available information.

1 And on day one of the meeting, each of the
2 review teams goes through everything separately.

3 Q At the conclusion of the first day -- strike
4 that.

5 Do the two teams spend the entire first day in
6 their separate groups?

7 A Yes. I mean, sometimes one team will make it
8 until five o'clock. Another team might actually finish
9 by a little before 4:00. They work at slightly different
10 paces, but, yeah, they spend the whole day at it.

11 Q Before the members of the expert review panel
12 come together for those meetings, what types of materials
13 have they received and how long have they had them?

14 A We usually ask that question in terms of how
15 many boxes that we send them. It's just -- it's
16 everything. It's the draft report, which is usually the
17 least of it.

18 Any unpublished data that Monice and Ivan and I
19 had included in that draft report, the panel got the full
20 unpublished data. The panel developed the practice of
21 telling us, "Don't send us the published studies."
22 Because, frankly, we're all back home here at academic
23 institutions and it's really easy to do one of two
24 things: either just get on the internet and pull up
25 the study, because our access at the library allows us to
26 just do that; or, we can get a copy printed out from the
27 university library.

28 So they said, "Don't send us the published

1 studies; we'll get those on our own."

2 But we have to send them the unpublished data
3 because they're unpublished. I mean, nobody else has got
4 them. So they get all of that to look at. They get
5 whatever input was provided to CIR from outside -- all
6 those comments on the SLR, the comments themselves were
7 provided to the expert panel so that they could see what
8 was said and, arguably, could act as a quality control on
9 CIR. So if CIR said, "well, I don't think this change is
10 needed technically," the panel can look at what was
11 suggested and say, "CIR, make the change."

12 So it provided everybody with all of the
13 information.

14 Q So taking us back to the meeting, we went
15 through the first -- got through the first day. What
16 happens at the second day of the meeting?

17 A The second day, the full panel convenes, all
18 nine people. And, one by one, they go through the safety
19 assessments that were on the agenda for that meeting.

20 Q Who presides at that meeting on the second day?

21 A Dr. Wilma Bergfeld runs the meetings.

22 Q As CIR director, did you attend the expert panel
23 meetings?

24 A Yes.

25 Q And I'm asking relating to talc, of course. Did
26 you attend --

27 A Well, I attended every one, talc or not.

28 Q Did you review all of the material that had been

1 provided to the expert panel?

2 A Yes.

3 Q Did you participate in the discussions with the
4 expert panel?

5 A I did.

6 Q Did you have a vote?

7 A No, I don't have a vote, but I get to talk.

8 Q What happened at the December 2012 expert panel
9 meeting -- I'm directing your attention to the second
10 day -- with respect to talc?

11 A I can't -- I'd have to really look at the
12 transcript to see which team moved to declare that talc
13 was safe in the present practices of use. But it's
14 usually one of the team leaders makes a motion and the
15 other team leader seconds it.

16 And then they go into a discussion of anything
17 that they think needs to be said regarding the motion to
18 reach a conclusion. And that's usually substantial.
19 "Here is what we want to see in the discussion."

20 They don't sit there in the meeting and actually
21 write the discussion, but they do talk about what they
22 want to see in the discussion that supports their
23 decision to reach this tentative conclusion.

24 And in our parlance, that tentative conclusion
25 is an important step. It's not done. We're tentatively
26 saying this is what we think the right answer is for this
27 particular ingredient or ingredient group.

28 Q Is that tentative conclusion that you just

1 referenced something called a tentative safety
2 assessment?

3 A That's correct.

4 Q The tentative safety assessment for talc was
5 published approximately when in 2012?

6 A Ten days after the meeting, so December 18th or
7 so. I'm not sure I remember the exact day, but it was
8 mid-December of 2012.

9 Q Is there a comment period after the tentative
10 safety assessment is prepared?

11 A Yes. Again, that's part of the procedures.
12 There's an opportunity -- a 60-day comment period for
13 anybody that wants to provide input to CIR.

14 Q Did the expert panel receive comments on the
15 tentative safety assessment?

16 A Yes, we did.

17 Q Did it receive comments from industry?

18 A Yes.

19 Q What sorts of comments?

20 A A lot of comments, most, again, highly
21 technical, relating to how things were organized and what
22 study should be put where. There were technical comments
23 on one particular study on cocarcinogenesis of a chemical
24 called benzo[a]pyrene. And in the draft report, the
25 staff and the panel had used a description of the assay
26 involved that was really quite old.

27 And the technical comment came in from the trade
28 association that, in fact, there was newer information

1 available about how you think of this as a potential
2 cocarcinogen.

3 And the trade association recommended that we
4 just delete all reference to that because it was no
5 longer relevant. That's an example of the kind of input
6 that was received.

7 Q Did all of the information that the CIR received
8 from industry become available to the public?

9 A Yes.

10 Q How, if at all -- or how would you characterize,
11 Dr. Andersen, the impact that industry comments had on
12 the evaluation being conducted by the expert panel?

13 A On the evaluation, not much. I mean, it's
14 always useful if somebody can find a technical issue that
15 ought to be fixed or improved. As I think of it, that
16 doesn't really impact on the actual evaluation; that just
17 improves the quality of the document. You know, a
18 comment -- another comment I recall we received was, "You
19 should really expand" -- the comment wasn't "expand" --
20 the comment was, "You should change how you describe what
21 talc is."

22 And you know, we read that, and we looked at
23 what they were saying, and, yes, this is another way of
24 describing the structure of talc and explaining why it
25 actually works to reduce friction. But the -- the
26 chemist on the CIR staff said that's -- that's not the
27 right way to do it and our way was wrong; it's just
28 another way of saying it.

1 So, yeah, it seemed like a good compromise. But
2 that -- that doesn't rise to the level of saying, did it
3 influence our evaluation? No, I don't think we received
4 much input that really influenced the evaluation.

5 Q Was there a final draft report that went to the
6 public? And, if so, when was it published?

7 A Okay. Well, that's -- that's the next step. So
8 we're in December of 2012, and we've issued this
9 tentative safety assessment with a 60-day clock. Talc
10 was scheduled to be reviewed at the March 2013 meeting,
11 which, you know, in preparing for the meeting meant that
12 sometime early February, we really wanted to hear from
13 any interested party so we could provide that information
14 to the expert panel.

15 Nobody is ever timely. We got some -- I mean,
16 not unsubstantial, but we got some input by the deadline
17 we had set, because we got to package this stuff, put it
18 in boxes, and sent it off to the panel again for them to
19 review it. We got some information that came in very
20 late. And in the panel's lovely parlance, it developed a
21 life of its own. There was a wave two package of
22 documents. And, again, it was a lot easier this time
23 because we were doing everything electronically. So
24 there was a draft -- you know, I should back up. I'm not
25 being as clear as I otherwise could have.

26 In response -- we've got the tentative safety
27 assessment. We receive input. What Monice and Ivan and
28 I did was take all of that input and prepare a draft

1 final, because that's going to be the next step. The
2 draft final then is part of this electronic package that
3 goes out to the panel. All the comments go out to the
4 panel. And then, wave two, all of the comments that came
5 in late go out to the panel. But all of that's on the
6 website, the comments. The panel has it, the public has
7 it. Nothing is not public.

8 Q Let me stop you there for a moment. Is there
9 any point in time when the members of the panel actually
10 provide line edits on any of these draft reports that we
11 have been discussing?

12 A Oh, they provided line edits at each of the
13 stages. When we sent them that draft report in December,
14 I could have a red ink franchise for the comments that
15 come back of providing us input. I mean, it's not
16 negative input. It's, you know, this is what I think of
17 this study. This is, you know, my particular expertise.

18 That then occurred on the draft final safety
19 assessment that we sent out in preparation for the March
20 meeting. Every chance they get, a draft -- a report,
21 they mark it up.

22 Q So do you remember the date of the March meeting
23 that you just referred to?

24 A Uh --

25 Q Sometime in March of 2013.

26 A Yeah. No, I don't remember the actual days.

27 Q And that was the second expert panel meeting
28 relating to talc?

1 A That's correct.

2 Q Did -- is there an opportunity for members of
3 the public or industry to speak at that meeting?

4 A Yes, they're open public meetings.

5 Q Did industry members speak at that second
6 meeting, the March 2013 meeting?

7 A Yes, there were industry representatives who
8 spoke.

9 Q Do you recall who spoke?

10 A No.

11 Q Do you recall how long they were given to speak?

12 A Oh, it turns out that -- at this meeting, there
13 were no formal presentations. As part of the panel
14 discussions, there were questions about information that
15 the panel had asked to come in from industry, and there
16 was dialogue about what is this we got, what does it
17 mean, et cetera.

18 So industry, as any member of the public, is
19 actually invited to participate in the open panel
20 discussion. It's not just the panel; it's anybody that
21 wants can participate, preferably after they've raised
22 their hand and asked permission. But it's a
23 participatory process, and there were some industry
24 inputs during that.

25 Had somebody asked for time to make a formal
26 presentation, that time would have been granted. And I
27 think I usually recommended that that be no longer than
28 an hour, preferably less.

1 Q Mr. Bales, could we publish page 3 again, which
2 is the listing of the expert panel members again.

3 Dr. Andersen, did the comments that were
4 received by the expert panel -- either in the first step,
5 the draft report, or the draft final report -- did the
6 comments from industry or members of consumer groups,
7 whatever, in your view, impact the CIR expert panel's
8 evaluation in any way?

9 A Not in my view.

10 Q Was there a vote taken ultimately as to the
11 approval for that final report that was prepared?

12 A Yes, it was unanimous.

13 Q When was that vote taken?

14 A The second day of the meeting in March,
15 whichever day that was.

16 Q After that vote -- strike that.

17 At the time that vote is taken, is the report in
18 a final form or there's work to be done still after the
19 second meeting?

20 A There's work to be done still. The panel
21 discussion almost always includes some element of
22 tweaking of the discussion section that they had
23 reviewed, not so much in the body of the report, but the
24 discussion section is just always tweaked to some extent.

25 And each panel member, again, has done their
26 markups of technical comments. And the routine statement
27 is, "well, yes, I've made technical comments on the
28 document. I'm very comfortable. The CIR staff can just

1 deal with those technical comments. They aren't anything
2 that we need to discuss as a full panel."

3 Just about everybody goes through that litany.
4 All the panel members make some version of that piece of
5 input. And then they reserve their time for talking
6 about the things that they actually think are significant
7 to talk about.

8 Q Was there any discussion at the second meeting,
9 the March meeting from 2013, regarding the use of talc on
10 broken skin?

11 A Yes, that was a discussion.

12 Q Can you relate that to the jury.

13 A Well, from the very beginning, the panel had
14 acknowledged that there is information that suggests that
15 if talc is applied to an open wound, that there is the
16 possibility that a granuloma can form. The panel didn't
17 consider that a significant finding of concern because
18 talc is just not applied to skin that has got an open
19 wound on it.

20 But the panel really wanted to mention that and
21 they did so. And they talked about, "Just how do you say
22 it?" And it turns out it's not as easy to say as you
23 would think it is. I mean, the concept was if the skin
24 is intact, you're home free. Now, how do you talk about
25 skin not being intact?

26 Q Did the final report include the discussion of
27 the language that was ultimately worked out with respect
28 to granulomas?

1 A That's correct. It did.

2 Q When was it that the final report was actually
3 buttoned up and put in final form?

4 A I think it was about a week and a half, no more
5 than two weeks after the meeting.

6 Q Let me ask you to take a look at Exhibit L384 in
7 your binder.

8 A Okay. That's what we just did, yeah.

9 Q Is Exhibit L384 the final version of the report?

10 A It's the final final version.

11 Q Okay.

12 A You know, I described earlier the mission of the
13 CIR kind of at the end of it was that phrase "and publish
14 in the peer-reviewed literature." well, the CIR safety
15 assessment that was late -- mid-March of 2013 was the
16 final CIR safety assessment. And that was published on
17 the website. And anybody who wanted to look at it can
18 look at it. So the final safety assessment was done.
19 But we have one more step. And that is the
20 organization's commitment to publishing it in the
21 scientific literature.

22 Not everybody knows to go to the CIR website to
23 get this information. And we were committed to
24 publishing it so that as many people as possible would
25 have access to it. That's what this document is.

26 Q So the final report was published on the website
27 in 2013; am I right?

28 A That's correct.

1 Q And the final final, as you've described it, is
2 the document in front of you, L384, which was published
3 in 2015?

4 A That's correct.

5 Q Was it published in the International Journal of
6 Toxicology?

7 A That's correct.

8 Q Is that a well-regarded scientific publication?

9 A That's a -- I think it's well regarded. For us,
10 one of the hallmarks of submitting for peer review at the
11 International Journal of Toxicology is the first word,
12 "international." We really like to get this word out
13 as -- just widely as possible so that anybody who wants
14 can see what we have done and agree, disagree. But at
15 least we get out this information so that it's widely
16 available. And international seemed like a really good
17 idea.

18 Q And take a look at the first page of Exhibit
19 L384.

20 And no need to publish it, Mr. Bales.

21 I just want to establish the authors of the
22 final report. I see a number of names there. Can you
23 describe -- you don't have to list the names, but just
24 describe who the people were as -- from categories who
25 are actually listed as authors of the final report.

26 A Okay. Well, it's -- it's Monice Fiume and Ivan
27 Boyer who did most of the heavy lifting. It's all of the
28 members of the CIR expert panel because they put their

1 scientific imprimatur on it. And it's me because I was
2 orchestrating the whole thing.

3 Q And that is it? It's the seven -- excuse me --
4 the nine folks who are on the board, the two staff
5 members, and yourself?

6 A Yes. I hope it adds up to 12. It's supposed
7 to. Nine and three, yes.

8 Q Did you help to prepare a demonstrative that
9 states the conclusion that was set forth in the CIR final
10 report?

11 A I believe I did.

12 MR. WILLIAMS: Your Honor, permission to publish
13 slide 5?

14 THE COURT: Mr. Smith?

15 MR. SMITH: Can I take just a second, your
16 Honor?

17 THE COURT: Yes.

18 MR. SMITH: Thank you.

19 No objection.

20 THE COURT: Thank you.

21 MR. WILLIAMS: If we could publish that,
22 Mr. Bales, slide 5.

23 No, 5. This one here.

24 I can use the ELMO. Just switch over. My
25 apologies.

26 Q BY MR. WILLIAMS: Dr. Andersen, is this the
27 conclusion that was reached by the CIR panel?

28 A That is the conclusion they reached.

1 Q Could you read your slide.

2 A "The CIR expert panel concluded that talc is
3 safe for use in the present practices of use and
4 concentration as described in the safety assessment."

5 Q Do you still have Exhibit L384 in front of you?

6 A Yes, I do.

7 Q Could you turn to the end of that document and
8 tell the members of the jury the number of references to
9 literature that are listed there.

10 A There are 218 citations.

11 Q Dr. Andersen, in the published report which was
12 published in the International Journal of Toxicology, did
13 the CIR explain its rationale for its conclusion that
14 talc is safe?

15 A Yes, it did.

16 Q Did the report set forth in summary fashion
17 the -- its reasoning?

18 A Yes, it did.

19 Q Did it do that in bullet point form and in text
20 form?

21 A It did it both ways, yes.

22 Q Have you prepared a slide that sets forth in
23 bullet point form the bases for the conclusions?

24 A Yes, I did.

25 MR. WILLIAMS: Your Honor, permission to publish
26 page 9 of the slides we provided?

27 THE COURT: Any objection?

28 MR. SMITH: No objection.

1 THE COURT: Thank you.

2 Q BY MR. WILLIAMS: And if you would, Mr. Bales,
3 let's pull out the top half if we can, just to make it so
4 it's a little bit bigger, if there's any way to make it
5 bigger.

6 At the top, Dr. Andersen, it says "critical
7 issues that called into question the validity" -- can you
8 folks read that, the top line?

9 THE COURT: Can everyone see that?

10 Q BY MR. WILLIAMS: It says, "critical issues that
11 called into question the validity of the statistically
12 significant associations."

13 what is that referring to?

14 A The panel had spent page after page after page
15 going through the available epidemiology studies that
16 looked for an association between talc and ovarian
17 cancer. And this is now, at the end of all of that,
18 "Here is what we think."

19 Q The first thing that's listed here is "absence
20 of persuasive evidence that talc can migrate from the
21 perineum to the ovaries."

22 And would it be accurate to say that there are
23 some studies that say talc could migrate, some could not?
24 Is that accurate?

25 A Well, I think that was certainly the sense of
26 the CIR expert panel. They had the view that --

27 MR. SMITH: Object, your Honor. This is
28 hearsay. I mean, if he wants to state personal

1 knowledge -- I mean, this is the expert panel. And it
2 says what it says in the report. Hearsay.

3 THE COURT: Sustained.

4 Q BY MR. WILLIAMS: Let me ask you, based upon the
5 review that you heard and the studies that you saw cited,
6 what is your view on the issue of migration?

7 MR. SMITH: I'm going to object. We haven't
8 established that he has gone through and done all the
9 review of migration. It's the expert panel, he said, did
10 all this.

11 THE COURT: Sustained.

12 Q BY MR. WILLIAMS: Dr. Andersen, did you
13 participate in the discussion of the expert panel with
14 respect to each of the nine bullet points that are
15 appearing on the screen?

16 A Yes, I did.

17 Q Did you read the studies that supported all of
18 the discussion that took place at both the initial
19 meeting of the panel and the second meeting?

20 A Yes.

21 Q Were you present --

22 A I do that with every safety assessment.

23 Q Were you present for all of the discussion as it
24 related to migration that occurred?

25 A Yes.

26 Q Did you read studies relating to it?

27 A Yes.

28 Q What was your view regarding the issue of

1 migration?

2 MR. SMITH: I'm going to object, your Honor, as
3 outside the scope of his report. This is not in his
4 report.

5 MR. WILLIAMS: Actually, this bullet point that
6 I'm asking Dr. Andersen about is in the report, your
7 Honor. I think it's on page --

8 MR. SMITH: If he can show it to me, that's
9 fine. I don't have a problem. I could be mistaken.

10 THE COURT: Bear with us for just a minute,
11 folks.

12 MR. WILLIAMS: Your Honor, it's on page 54 of 64
13 of Exhibit L384. It's the very first bullet point.

14 MR. SMITH: Excuse me. That's the CIR report?

15 MR. WILLIAMS: Correct. It's Exhibit L384.

16 THE COURT: I think Mr. Smith is making a
17 reference to Mr. Andersen's litigation report.

18 MR. SMITH: That's correct.

19 MR. WILLIAMS: Oh, I'm talking about Exhibit
20 384.

21 THE COURT: I think Mr. Smith is talking about
22 the report that Mr. Andersen wrote.

23 MR. WILLIAMS: Oh, understood. I understand.
24 It's Dr. Andersen.

25 THE COURT: Sorry.

26 Q BY MR. WILLIAMS: Dr. Andersen, did you in your
27 report discuss the -- did you incorporate by reference
28 the CIR report in your report?

1 A Um --

2 Q In other words, did you reference --

3 A I talked about it as the basis for -- for my
4 expert report in this -- in this case.

5 Q Is the CIR report, the final report, attached to
6 your expert report in this case?

7 A Yes, it was.

8 Q Does the CIR report that was attached to your
9 report in the case include the bullet points that are set
10 forth on the slide that the jury is viewing now?

11 A Yes, it did.

12 Q What was your view regarding the absence of
13 persuasive evidence that talc can migrate from the
14 perineum to the ovaries?

15 MR. SMITH: And again, your Honor, none of these
16 opinions are expressed in his report, in the four corners
17 of his report. I understand what the CIR did, but the
18 panel, he expressly said, did the review, not him. So I
19 object. This opinion about transmigration is not in his
20 report.

21 THE COURT: Overruled.

22 Q BY MR. WILLIAMS: Go ahead, Doctor.

23 A It was the sense of the panel that those
24 available data just simply did not reliably demonstrate
25 that talc could move from the outside of the body, at the
26 perineal area, inside the body and end up in the ovaries.
27 And, certainly, part of that was the panel's clear
28 acknowledgment that there's just no data on the first

1 step of that process, of talc going from the outside
2 getting into the vaginal cavity.

3 Q Let me ask you a separate question.

4 Was the conclusion of the expert panel that talc
5 is safe contingent on a finding that talc -- that talc
6 could not migrate, meaning did the panel conclude that
7 talc is safe but basing that on the notion that there's
8 no way that talc could get to the ovary?

9 MR. SMITH: Objection, your Honor. Hearsay. He
10 said he was not a voting member on the panel.

11 THE COURT: Sustained as phrased.

12 MR. SMITH: Thank you.

13 Q BY MR. WILLIAMS: Were you present for all of
14 the discussion regarding migration and all of the other
15 issues that are set forth on the board regarding talc?

16 A Yes, I was.

17 Q With respect in specific regard to this first
18 bullet point, the issue of whether or not talc can
19 migrate, did you listen to the discussion of the panel
20 members?

21 A Yes, I did.

22 Q Did you review the edits that they suggested to
23 the final report before the report was made final?

24 A Yes.

25 Q Was it your job to do that?

26 A That's -- yes.

27 Q Did you receive edits from members of the panel
28 in preparing the final report which included the bullet

1 points that are on the board right now?

2 A Yes.

3 Q With respect to the issue of migration, was the
4 conclusion of the panel that talc was safe contingent on
5 the notion that talc could not migrate?

6 A Um --

7 MR. SMITH: Your Honor, I'm going to object
8 again. It's hearsay.

9 THE COURT: Overruled.

10 THE WITNESS: The panel's finding was certainly
11 based on its understanding that it just isn't very likely
12 that talc moves from the outside in the perineal area up
13 to the ovaries.

14 Q BY MR. WILLIAMS: Let me refer you to the second
15 bullet here, which is "Lack of consistent statistically
16 significant positive associations across studies."

17 what are the types of studies that this bullet
18 point refers to?

19 A The CIR safety assessment included available
20 case-control epidemiology studies, cohort studies. They
21 looked at -- prospectively at large populations and
22 packaged all of that information together into a rather
23 large section presenting the epidemiology data.

24 Q What was the basis for the conclusion that there
25 was a lack of consistency regarding significant positive
26 associations across the study?

27 A It -- it wasn't hard. Some studies showed a
28 positive association between the use of talc and ovarian

1 cancer, and other studies said there isn't an association
2 between the use of talc and ovarian cancers.

3 The panel looked at that and said, there's a
4 lack of consistent positive association across studies.
5 Some do; some don't.

6 Q Let me direct your attention to the phrase
7 "statistical significance." Do you have that phrase in
8 mind?

9 A Yes.

10 Q With respect to the case-control studies that
11 were available to the panel at the time that you and
12 others drafted the CIR report, do you have any recall
13 regarding the relative number of studies that show a
14 statistically significant association and those that did
15 not have statistically significant findings?

16 A Yes. I think it's -- as we talked about this in
17 the panel meetings and at the -- I mean, it's all -- it
18 looks pretty obvious when you package it up. It's pretty
19 close to half and half.

20 Q What significance did that have, half
21 statistically significant and half -- half not
22 statistically significant and half of the studies being
23 statistically significant?

24 A For the panel, it loops back to that sentence at
25 the top ending with a colon. It calls in to question --

26 MR. SMITH: Your Honor, excuse me. I just want
27 to object. He's speaking on behalf of the panel. It's
28 clear hearsay.

1 THE COURT: Overruled.

2 MR. SMITH: Okay.

3 THE WITNESS: The lack of consistent
4 statistically significant positive associations was part
5 of what contributed to that view that maybe the
6 statistically significant associations aren't really
7 valid.

8 Q BY MR. WILLIAMS: You have significant
9 experience with epidemiological studies?

10 A Over my career at FDA and during my work at CIR,
11 regular consideration of epi studies.

12 Q When the results of a study are not
13 statistically significant, what is the significance of
14 that to you?

15 I don't mean to overuse the word, but what does
16 that mean to you?

17 A Well, it means that you haven't demonstrated
18 what you started out to demonstrate. In the case of a
19 study that looks at a possible link between the use of
20 talc and ovarian cancer, you haven't made the case that
21 these are linked, that there is an association.

22 Q Let me direct your attention to the third
23 bullet. The third bullet says, "Uniformly small risk
24 ratio estimates in studies reporting positive
25 associations."

26 Do you see that?

27 A Yes, I do.

28 Q Why the use of the phrase "small risk ratios"?

1 A Well, that, in all of our discussions, was the
2 way in which the available studies seemed to be best
3 characterized. These -- where there was a positive
4 association, it -- just for use of a number, it was in
5 the range of 1.3. And in the discussions, the panel
6 basically referred to that as a -- a small relative risk
7 or odds ratio, whichever way it was captured, a small
8 increase.

9 Q Let me direct your attention to the fourth
10 bullet. The fourth bullet says, "Failure to rule out
11 plausible alternative explanations of the statistically
12 significant results including biases, confounding risk
13 factors, and exposure misclassifications."

14 Please describe that section and that point.

15 A Well, as was talked about at all of the
16 discussions, this is the other shoe, if you will.

17 The previous bullet said that the -- when there
18 was a positive association, it just wasn't that big. But
19 when it's not that big, you really start to ask the
20 follow-up question: How could that be wrong? You know,
21 you accept that there's a positive association, it was
22 statistically significant, but it's not very big. Why
23 could that be wrong?

24 And what the panel -- I think epidemiology in
25 general looks at is what might the biases be in
26 collecting those data. Recall bias is a not-uncommon
27 bias to consider in looking at epidemiology data. How
28 well can you actually remember what happened 15 years

1 ago.

2 Q When a --

3 A During the discussion, there was also an
4 acknowledgment that there may be confounding risk
5 factors, other things going on, that might actually be in
6 play, and talc might not be the real association.

7 The panel repeatedly -- I mean the
8 discussions -- repeatedly acknowledged that in each of
9 these case-control studies, most of the women with
10 ovarian cancer had never used talc.

11 So something else other than talc has to be at
12 play here. So the idea that there would be confounding
13 risk factors was acknowledged, and then finally the
14 possibility of exposure misclassifications. I mean, it
15 could be as simple as was it talc or was it cornstarch?
16 Do I really remember?

17 And absent a sense of how good those
18 recollections are, it's possible to think that a small
19 statistically significant finding might actually go away
20 if you had better data.

21 Q Let me direct your attention to the fifth bullet
22 which says, "Absence of statistically significant
23 associations between ovarian cancer and using talc-dusted
24 diaphragms or condoms."

25 why was that significant?

26 A During the discussion, it was noted -- this
27 almost refers back to that first bullet -- but the panel
28 was thinking that, you know, if a partner uses a condom

1 that's talc-dusted or the woman herself uses a diaphragm
2 that's talc-dusted, what happens is that the talc is now
3 closer to the ovary. You don't have that question any
4 longer of does it get inside. It's already inside.

5 And the panel considered that, okay, that's good
6 to know. So the ability to get to the ovaries has to be
7 increased. I mean it's closer. And when those
8 circumstances didn't lead to an increase in ovarian
9 cancer, the panel and myself included thought that was
10 significant.

11 Q Let me direct your attention to the sixth bullet
12 point which says, "Overall lack of positive
13 exposure-effect relationships."

14 Does this refer to dose response?

15 A Yes, that's what we are trying to talk about,
16 the more exposure, the more effect.

17 I'm not sure I know how to amplify on this.
18 It's just the overall view of these positive
19 exposure-effect studies. Certainly not all of the
20 epidemiology studies provided -- excuse me -- provided
21 information on the extent of the exposure. Some were
22 just did you ever use talc or you never use talc? That
23 doesn't tell you much about the extent of exposure.

24 But some studies asked how frequently did you
25 use talc. Some studies asked over how many years did you
26 use talc. And those give you some handle on how much
27 exposure might have occurred. Unfortunately, none of the
28 studies asked how much talc do you use --

1 Q In terms of quantity --

2 A -- the third feature.

3 Q I'm sorry. I didn't mean to speak over you.

4 You said how much talc is used. Are you talking
5 there about the sheer quantity of talc that was applied?

6 A The magnitude, yeah.

7 Q Are there some studies that were reviewed and
8 available and cited in the report of the CIR that dealt
9 with both the frequency of a woman's use and the duration
10 or number of years of their use?

11 A Yes, there were some of those in the report.

12 Q Were those reviewed as well by the panel?

13 A Yes.

14 Q Let me direct your attention to the seventh
15 bullet. The seventh bullet reads: "Inverse trends for
16 both duration of use and frequency of use in some
17 studies."

18 what did that refer to?

19 A well, that's the -- again, the way we captured
20 this, this is the second shoe of the dose-response
21 discussion. When the data from a study that looked at
22 frequency of applications or duration, total duration of
23 use, when we looked at those -- I mean, I can't say every
24 place, but you would pick a study and look at it and find
25 a higher exposure, more frequent uses, longer duration of
26 use at a lower odds ratio than less frequency of use or
27 shorter total duration. And it just left us scratching
28 our heads.

1 Q why would the notion that longer use or more
2 frequent use having a lower risk ratio cause you and the
3 other panel members to -- and the others who worked on
4 the report to scratch your heads?

5 A It makes no sense.

6 Q Could you amplify?

7 A I'm sorry. Say again.

8 Q Could you amplify?

9 A In whatever probability you think might exist
10 for talc moving from the perineal area through the
11 vagina, past the cervix, through the uterus, up the
12 fallopian tubes, to get to the ovary, if there's more
13 stuff there to do that, then there ought to be more
14 consequence at the end of it, and a more frequent use in
15 concept ought to lead to more of the result. If you used
16 it over a lifetime, it ought to lead to more of the
17 result.

18 You know, again, unfortunately, the question of
19 how much you applied was just never legitimately captured
20 so that you can add that in. But then that now comes to
21 the surprise.

22 Wait a minute. If that should lead to more
23 consequence, it's less. It just doesn't fit a pattern of
24 what you would expect in a cause-effect relationship. It
25 just doesn't fit the pattern.

26 Q Let me direct your attention to the eighth
27 bullet point, which says, "Absence of a plausible
28 biological mechanism."

1 what was the focus of the discussion of the
2 panel members regarding biological mechanism?

3 A well, the focus was to turn the thinking around.
4 You know, just clearly the panel is not impressed with a
5 good bit of the data. That's clear from the bullet
6 points that they have given up to this point.

7 But what could possibly be going on with talc
8 that might actually suggest an ovarian cancer risk? How
9 biologically could that occur? what is it that talc
10 would do even if it did get to the ovaries?

11 So the panel really looked at that question.
12 You know, it didn't believe that it would easily get to
13 the ovaries, but they posed that question. Suppose it
14 did? what mechanism do we know about that could suggest
15 that?

16 And the -- the view of -- you know, I went
17 through the background of the panel members. I think it
18 adds up to well over 200 years of research experience in
19 cancer causation. They looked at it and said, there's no
20 plausible biological mechanism by which we think this
21 could happen.

22 Q Let me, if I could, for a moment, Doctor --
23 Could you put up the slide again? I believe it
24 was slide 3 which is the panel members.

25 I just wanted, for the sake of clarity,
26 Dr. Andersen, to have you point out the members of the
27 review panel who had those combined years of experience
28 in toxicology-type issues.

1 A Oh. It's Dan Liebler, Curt Klaassen, Tom Slaga,
2 and Ron Shank have all made their careers on researching
3 the question of cancer causation.

4 Q Let me ask you if there was any sort of
5 discussion -- if you could go back to the other slide,
6 which was the eighth bullet point there.

7 was there a discussion of what the studies that
8 were included in the reference materials said about tubal
9 ligation or whether there was any relationship or
10 association found in the studies where women had actually
11 had their tubes tied and any -- whether that affected an
12 association between talc use and ovarian cancer?

13 A Well, yes, that was part of the discussion.

14 The panel looked at that subset of epidemiology
15 studies that reported results in women who had undergone
16 a tubal ligation. And at least in concept, the -- the
17 temporal issue of when did they have it, when were they
18 exposed, put that aside for a moment, but tubal ligation
19 ought to prevent talc from getting to the ovaries.

20 And the panel looked then at those studies and
21 it was a mixed bag. Some of them in which this blockage
22 that should have prevented any exposure to the ovaries,
23 there was some data that suggested there was still a
24 positive association. It didn't make a lot of sense, but
25 it was what it was. But there were other studies that
26 showed that, when you blocked this, the odds ratios went
27 down.

28 Q What does that say -- the phenomenon that you

1 just described in the studies -- what does that say about
2 whether the risk ratios or odds ratios that were then
3 looked at could be viewed as establishing a causal
4 connection between the use of talc and ovarian cancer?

5 A Well, in the panel's discussion of how these
6 associations between exposure to talc and from the epi
7 studies might be linked to the endpoint of actual ovarian
8 cancer, to assert that talc causes it when a tubal
9 ligation has blocked the passage, seemed to call that
10 into serious question.

11 Q Let's turn to the final bullet. The final
12 bullet says, "Lack of credible defensible evidence of
13 carcinogenicity from the results of epidemiological
14 studies of occupational exposures and animal bioassays."

15 My question is this: Did the panel, the expert
16 panel, review animal studies that had been done in the
17 area of talc in connection with ovarian cancer?

18 A Yes, they did.

19 Q Did the panel review studies that dealt with
20 human -- strike that.

21 Did the panel review studies dealing with
22 subjecting human ovarian cells to talcum powder?

23 A Yes, those cell studies were included.

24 Q Describe for the jury the level of experience of
25 the people on the expert panel in reviewing animal
26 studies and human cell studies and carcinogenicity.

27 A Well, I gave you the figure of 200-plus years of
28 research experience in -- in looking at cancer causation.

1 You can add to that the 30 years of research experience
2 from Paul Snyder and the 20 years of research experience
3 from Ron Hill looking at cellular and animal studies.

4 Q Let me direct your attention to an animal study
5 that has been discussed a lot in this courtroom.
6 Specifically it's the NTP, National Toxicology Program,
7 rat inhalation -- it's actually rat and mice --
8 inhalation study from 1992.

9 Are you familiar with that study?

10 A Yes, I am.

11 Q I'll direct your attention in your book to
12 Exhibit L938.

13 A Yeah, these are in order. Yeah, there it is.
14 Okay.

15 Q This is the rather lengthy study relating to rat
16 inhalation; correct?

17 A Yes, it is.

18 Q Did the expert panel from CIR review that study
19 in its entirety?

20 A In depth.

21 Q Let me represent to you, Dr. Andersen, that one
22 of the experts called on behalf of Ms. Echeverria,
23 Dr. Plunkett, suggested that the rat inhalation study
24 from 1992 was a useful study to see the effects that talc
25 would have on the lungs of the rats at various points in
26 time.

27 Based upon the expert panel's review of that
28 study and comments on that study by other parties, what

1 can you tell the jury regarding the usefulness to the
2 panel of the rat inhalation study?

3 MR. SMITH: Your Honor, this is not mentioned in
4 his report, and he's not on the expert panel. I object.

5 THE COURT: I think the question as phrased is
6 inappropriate. It's sustained.

7 First of all, it's a narrative; and, secondly,
8 it's one thing to ask him what the panel concluded. It's
9 another thing to ask whether some of the panel found it
10 useful.

11 MR. WILLIAMS: I'll rephrase, your Honor.

12 Q BY MR. WILLIAMS: Did the expert panel review
13 this study?

14 A Yes, they did.

15 Q Was there a discussion of the study in the
16 report that is attached to your report?

17 A Yes, it was discussed in the CIR safety
18 assessment.

19 Q This study specifically?

20 A That's correct.

21 Q Was the discussion of the report that is
22 reflected in the CIR report that is attached to your
23 expert report in this case express the feelings of the
24 expert panel regarding this study?

25 A Yes, it did.

26 Q Were you present for the discussion of the rat
27 study when the CIR met on those occasions?

28 A Yes, I was.

1 Q All I'm asking is if you could describe the
2 impact, if any, of the rat inhalation study on the
3 conclusions of the panel.

4 MR. SMITH: Your Honor, that calls for
5 speculation.

6 THE COURT: Overruled.

7 THE WITNESS: The -- the panel discussion was
8 very clear that this study did not demonstrate a lung
9 toxicity for inhaled talc.

10 Q BY MR. WILLIAMS: why?

11 A Well, there were two primary reasons, both
12 highly technical, and then relating to how the study was
13 done. The first is the talc exposures that were actually
14 done were done by creating talc in really tiny particles.
15 And the panel I think acknowledged that nobody had a
16 choice but to do that because if they weren't really tiny
17 particles, they weren't going to get into the lungs of
18 the mice or rats. So there was a logic to why it was
19 done, the panel understood that.

20 But by doing that, the study created an
21 artificial exposure circumstance that, in the view of the
22 panel, just totally overloaded the lungs of the poor
23 animals. So that was the first point that the panel came
24 to.

25 The second point is -- is more nitpicky but
26 related to the conduct of animal studies. There were
27 periods during this lifetime exposure, a hundred and some
28 weeks these animals were treated to this insult, and in

1 different periods of time the exposure simply got out of
2 control. It -- in one case it skyrocketed for seven
3 weeks to well above the level that in parlance of people
4 who do these animal studies call the maximum tolerated
5 dose.

6 And, as a rule, when certainly Paul Snyder
7 jumped in on it in terms of his veterinary pathology
8 expertise, but in general, it's pretty understood, when
9 you exceed the maximum tolerated dose, the effects that
10 you see are not necessarily related to the agent in
11 question. They relate to having exceeded this dose.

12 So interpreting the findings, which were one of
13 the two species and one of the two sexes had some
14 evidence of cancer, what the panel said is, we can't
15 trust that. First of all, the exposures were massive. I
16 think -- I'm not sure it was ever captured in the
17 transcript, but the notes I recall seeing said you could
18 have done this with dust bunnies and gotten the same
19 result. This doesn't tell you about talc. It tells you
20 about overloading the ability of the mice and rats to
21 really process this kind of insult.

22 So those were the two factors that the folks who
23 conducted the study acknowledged that this existed. They
24 just concluded that you can still rely on the findings.

25 Q Let me stop you there for a moment.

26 The criticism -- that's my word. Strike that.

27 The view that you just expressed of the NTP rat
28 study that the panel had that we just can't trust -- that

1 was the words you used -- was that view consistent with
2 reference materials that are included in the CIR report
3 regarding what other bodies thought about the NTP rat
4 study?

5 A Yes.

6 Q Let me refer you to the exhibit that you've had
7 in front of you, Exhibit L384, which is the final final
8 report that was published in the journal. Do you have
9 that in front of you? Again, it's L384.

10 A Yes.

11 Q Let me direct your attention to page 58 of
12 Exhibit L384. Is that one of the pages where the
13 references are listed?

14 A That's correct.

15 Q And that's the 218 references you mentioned
16 earlier today?

17 A That's correct.

18 Q Let me direct your attention to reference number
19 11 on page 58. Do you see that?

20 A Yes, I do.

21 Q And does that refer to one of the -- strike
22 that.

23 Does that refer to the proceedings of the
24 Bethesda, Maryland, workshop relating to consumer uses
25 and health perspectives on talc?

26 A Yes.

27 Q Was that one of the references that was reviewed
28 by the panel?

1 A Yes, it was.

2 Q Was the view that you just expressed, the view
3 of the nine members of the panel that you described,
4 consistent or inconsistent with the views of the NTP talc
5 study set forth in Reference Number 11 to the report?

6 A Yes, it was.

7 Q One of the studies about which there's been
8 discussion is a study called Hamilton. Are you familiar
9 with the Hamilton study that was done relating to
10 injecting rats into the ovaries -- strike that --
11 injecting talc into the bursa of rat ovaries?

12 A Yes, that's part of the safety assessment of
13 which I'm an author.

14 Q Is that referenced in the references for the
15 final report of CIR?

16 A Yes, it is.

17 Q And, again, this is Hamilton 1984?

18 A I believe that's the date. I'm...

19 Q I'd ask you to comment on the notion -- strike
20 that.

21 Are you familiar with the difference between a
22 chronic exposure and an acute exposure to a substance?

23 A Yes, that's part of how we organize our reports.

24 Q Is that dichotomy, chronic on the one hand and
25 acute on the other, something that you consider when
26 reviewing the safety of ingredients?

27 A Yes, it is.

28 Q You're familiar with the Hamilton study?

1 A I am.

2 Q Can you describe or do you recall the
3 methodology of the Hamilton study; that is, how talc was
4 introduced to the rats?

5 A Yes, I do.

6 Q Please describe.

7 A It's not a particularly pleasant experiment.

8 The rats were anesthetized and their abdomens
9 were opened and the ovaries were pulled out external to
10 the body. It was mentioned that the ovary that's
11 actually in the rat contained an inside and outside sac.
12 And that was truly the case.

13 What the researchers then did was they injected
14 a bolus amount of talc under that outside sac so it
15 didn't have to go through the sac, it went under it,
16 right onto the surface of the ovaries.

17 After they did that, they put the ovaries back
18 in the animal, sewed them up, and put them back in the
19 cage.

20 And as a function of time, after that, they
21 looked -- well, sacrificed is the word. They killed the
22 animals and looked at what changes had happened in the
23 ovaries. They look at two weeks, look at four weeks,
24 look at six weeks as a function of time and see what
25 happened as a result of the exposure to talc. And that's
26 what the study was.

27 Q And just getting to the point of it, did the
28 study show that there was an increased toxicity over time

1 based upon the exposure of those ovaries to the talc?

2 A Boy, I really don't like the word "toxicity."
3 what the study found --

4 Q Use the word that is appropriate. I'm sorry.

5 A -- was two things. They reported that the
6 ovaries were cystic. Cysts had formed on the surface of
7 the ovaries. The other thing they reported -- and that
8 wasn't all of the ovaries, just in some of the ovaries
9 they reported that.

10 They also found what they called papillary
11 changes in the surface of the ovary, and that was four
12 out of the ten -- four of ten animals. And that's what
13 they reported. So those were the findings.

14 Q Based upon your review of the Hamilton study,
15 was the type of exposure of the ovaries to talc, based on
16 the methodology there, an acute exposure? chronic
17 exposure? where in that dichotomy would you express it?

18 A I think it defies an easy categorization because
19 the impact of how they did the study was to create a
20 chronic exposure to the ovary.

21 Q How so?

22 A Remember talking about that bursa, it is a
23 barrier to stuff getting past it into the ovary? It's
24 also a barrier to stuff getting out. So now you have
25 that talc that was put into that space between that sac
26 and the ovary and now it's sitting there, day after day
27 after day.

28 So as I look at it, again, it doesn't fit the

1 normal mode of a chronic study. Normally a chronic study
2 is that you just keep adding more stuff, more stuff.
3 That's done because classically, whether it's animal or
4 human, you have to add more because they get rid of it.
5 So to keep it going, you have to add more.

6 In this case, it just sat there and exposed the
7 ovary continuously. That is as close to chronic as I can
8 think of.

9 Q With respect to the Hamilton study, were the
10 changes, if any, to the ovarian cells cancerous?

11 A The authors I think specifically noted that they
12 found no cancer in the ovaries.

13 Q And did that -- strike that.

14 Was that the finding throughout the lifetime of
15 the rats even if it was a rat that was sacrificed near
16 the end of its life?

17 A I don't -- I would have to go look at the study
18 to remember whether any really reached end of life. But
19 as long as the study went on, none of the animals
20 developed any cancers.

21 *[4:47 P.M.]*

22 MR. WILLIAMS: Your Honor, I was going to shift
23 to another study. Is this an appropriate time?

24 THE COURT: I would think so. All right. Let
25 me ask counsel a question, and then I will query the
26 jury.

27 Do you have matters to take up in the morning?

28 MR. WILLIAMS: Could I have one moment to ask,

1 your Honor?

2 THE COURT: Sure.

3 (A discussion is held off the record.)

4 MR. WILLIAMS: Your Honor, I think the answer is
5 yes, there is one matter we'd like to take up today, if
6 we could. But I do think in the morning we've got one or
7 two shorter matters to raise. So the answer is yes.

8 THE COURT: So the answer is yes. So should we
9 ask the jury to be here at 9:30? would that be better?

10 MR. WILLIAMS: That would be fine.

11 THE COURT: All right. So 9:30, folks,
12 downstairs. Thank you very much. Have a good evening.

13 Leave your notes. Do not discuss the case. Do
14 not do any research. Do not form your opinions until you
15 get into the jury room and have the opportunity to talk
16 to each other.

17 (Jurors excused.)

18 THE COURT: You are welcome to step down,
19 Doctor.

20 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
21 COURT OUTSIDE THE PRESENCE OF THE JURY:)

22 MR. WILLIAMS: Dr. Andersen, you can step out in
23 the hall.

24 (Dr. Andersen excused from the courtroom.)

25 THE COURT: Okay. Standing or sitting, as you
26 wish. I know everybody has been sitting for a while.

27 MR. SMITH: You don't mind if we stand?

28 THE COURT: I do not mind if you stand, and I

1 might do the same in a bit.

2 MR. WILLIAMS: Thank you, your Honor.

3 At this time, given that the plaintiff has
4 closed, the defense moves for a nonsuit. And we are
5 prepared to file a memorandum today. Permit me, if you
6 would, to state the basis for the nonsuit.

7 We seek judgment of nonsuit on the ground that
8 the plaintiff has failed to introduce evidence sufficient
9 to carry her burden of proof, and the allegations fail as
10 a matter of law on the following issues:

11 A. That defendants had a duty to warn;

12 B. That the defendants' alleged failure to warn
13 was a substantial factor in causing plaintiff's harm;

14 C. That defendants engaged in conspiracy or
15 could be liable for public advocacy;

16 D. That the defendants can be liable for
17 negligence per se, based on FDA regulations or for fraud
18 on the FDA;

19 E. That defendants can be liable on the basis
20 of general negligence independent from plaintiff's claim
21 for negligent failure to warn.

22 That's the first motion that will be filed.

23 The second motion is a partial nonsuit as to
24 punitive damages. The basis for that -- and in the
25 alternative, to the relief requested above, the
26 defendants seek partial nonsuit pursuant to Section
27 581(c) subsection (b) on the issue of liability for
28 punitive damages.

1 Finally, the third motion is partial nonsuit as
2 to defendant Johnson & Johnson, the parent company. We
3 believe that partial nonsuit pursuant to Section 581(c)
4 subsection (b) should be granted as to defendant J&J on
5 the ground that J&J cannot be liable for the alleged
6 conduct of its subsidiary, JJCI. And plaintiff has not
7 submitted sufficient evidence on which the parent company
8 could be liable.

9 We have the papers to be filed today. We would
10 ask that we set a hearing for this on, say, Monday --
11 Monday morning, if that would be appropriate for the
12 Court.

13 And I believe that is all I needed to say at
14 this point.

15 THE COURT: Mr. Robinson?

16 MR. ROBINSON: I think we're going to have
17 Mr. Wilson just talk briefly. And if there's going to be
18 a --

19 THE COURT: Sure.

20 Mr. Wilson?

21 MR. ROBINSON: If there's going to be a brief,
22 we will wait for the brief.

23 THE COURT: I'm assuming you would like to file
24 a brief.

25 MR. WILSON: We can, your Honor, but we will do
26 whatever the Court would prefer. We could argue it
27 orally if the Court would prefer that right now as well.

28 MR. WILLIAMS: We'd prefer that counsel and the

1 court read the briefs.

2 THE COURT: Well, I can't read the briefs today.
3 So if you would prefer to file a written brief, we could
4 do that. And you tell me when you'd like to do that. If
5 counsel wants to argue this on Monday, I'm thinking maybe
6 you ought to file your brief by Monday. And then we
7 could argue this on Tuesday morning.

8 That would be better, I think, because counsel,
9 I presume, has spent more than the last five minutes
10 writing the motion. And you'd probably like more than
11 tomorrow close of business to file your written response.

12 MR. WILSON: Mr. Webb and I were in the hallway
13 during the examination of Dr. Andersen. And I saw two
14 bankers boxes come in with that motion for nonsuit. I
15 know, traditionally, I believe a motion for nonsuit or
16 opposition has a 15-page limit. I don't know if the
17 Court is -- wants page limits here. I don't know what is
18 the specificity.

19 THE COURT: I haven't seen the motion, but I
20 hope it doesn't exceed the 15-page limit.

21 MR. WILLIAMS: I personally don't know whether
22 any of the three -- the three different motions --

23 THE COURT: And it might have the exhibits
24 attached to it.

25 MR. WILSON: I saw two bankers boxes and I got a
26 little bit scared.

27 MR. WILLIAMS: If they do exceed, then we would
28 be happy to file -- one of them does, your Honor. And so

1 we would seek leave to file beyond the limit.

2 THE COURT: Mr. Webb, how long is the motion?

3 MR. WEBB: I believe, your Honor -- and I have
4 been here this afternoon, so I haven't seen the final
5 draft, but I believe it's approximately 30 pages.

6 THE COURT: Okay.

7 MR. WEBB: But I would add, your Honor, that
8 most of that particular brief would be familiar to all
9 counsel involved because it addresses, in part -- it
10 addresses two things: one, the failure to demonstrate
11 a duty to warn; and, two, the causation issues that are
12 extremely familiar to all counsel involved in the case.

13 So I don't think the issues presented will be
14 drastically different than what counsel should already be
15 aware of.

16 THE COURT: Does the plaintiff want 30 pages?

17 MR. WILSON: Your Honor, it sounds like there's
18 actually three motions, one of which is 30 pages. And it
19 sounds as if the others are 15. So I think we're talking
20 more about maybe 60 pages. I don't know that we want to
21 try and compete on that level with page limits, but
22 whatever the Court prefers.

23 THE COURT: If you want to file a written brief,
24 you're invited to do that and file it by Monday. If you
25 want to take 30 pages, that's fine. If you don't, that's
26 okay too.

27 MR. ROBINSON: Your Honor, the question, at
28 least I have, is the 30 pages for the three briefs?

1 MR. WEBB: No, there's one that's approximately
2 30 pages, and then the other two, I believe, are less
3 than 10 pages each. They are much shorter, the punitives
4 and the Johnson & Johnson corporate structure briefs.

5 THE COURT: So it's entirely up to plaintiff's
6 counsel how you'd like to proceed in terms of briefing.
7 I will certainly give you leave to file a longer brief.

8 MR. WILSON: One concern that I have -- and, you
9 know, we've all kind of been thinking about jury
10 instructions and verdict form -- early on, we made a
11 request for the CACI 418 instruction based on negligence
12 per se, with the statute or regulation being 21 CFR
13 740.1(a), with then the language in CACI 418 that says
14 the plaintiff still has to prove causation, causation
15 being defined by what the Court has already identified,
16 CACI 430, or maybe it was 431 or 435, modified a bit.

17 Part of the concern that I personally have in
18 opposing a nonsuit at this point in time is I don't know
19 if that instruction is going to be given. And so,
20 therefore, I don't even know what claims are on the
21 table.

22 Usually, jury instructions like this are kind of
23 hammered out before this point in time. So I think it
24 might be helpful if we addressed jury instructions so we
25 could fairly oppose this motion to know what claims are
26 out there. For example, the CACI 400, general negligence
27 claim, or if it was going to be a CACI 1220 general
28 negligence claim, the 418 claim, as well as the 1222

1 failure to warn claim.

2 THE COURT: Mr. Williams?

3 MR. WILLIAMS: That might make sense, your
4 Honor. We put the 318 -- because, of course, we don't
5 know for certain what the Court's pleasure is going to be
6 on the negligence per se instruction. That's why the
7 brief treats that issue separately.

8 MR. WEBB: Yes, your Honor. And, you know, the
9 proposition that you have to have a finalized set of jury
10 instructions before you can argue or brief a nonsuit
11 motion, I don't think is actually accurate given that the
12 nonsuit always comes at the close of the plaintiff's
13 evidence.

14 And typically the jury instructions aren't
15 finalized until final charging conference just before
16 closing. So as Mr. Williams alluded to, what we
17 attempted to do in the longer of the briefs that
18 addresses the duty and the causation issues is to
19 address -- and part of the link, frankly, is to address
20 specifically the different arguments and causes of action
21 that plaintiffs have suggested are still in the case.

22 And we, of course, take the position that
23 they've failed to present evidence to permit those causes
24 of action to be in the case, if they were even ever
25 properly in the case to begin with.

26 So that really is the thrust of the longer of
27 the three motions.

28 THE COURT: So let me suggest the following:

1 Before we finalize what we're going to do here, why don't
2 we recess for the afternoon and give plaintiff's counsel
3 an opportunity to read the brief, and then I'd like to
4 read it as well. And then I think in the morning we
5 would have a better sense of how we should address this
6 because then you'll have had time to read it.

7 MR. WILSON: Thank you, your Honor.

8 MR. WILLIAMS: Thank you, your Honor.

9 MR. WEBB: Thank you, your Honor.

10 THE COURT: I think that's what we should do.
11 Did you leave a copy of the brief with the clerk?

12 MR. WEBB: We are filing it right now, your
13 Honor.

14 MS. ZUKIN: Has it been served?

15 MR. WEBB: He's serving it on you right now.

16 THE COURT: Is it on Case Anywhere? Is it on
17 Case Anywhere?

18 MR. WEBB: It will be, your Honor, as soon as we
19 have it filed. But we're prepared to serve it on Case
20 Anywhere right now. But we have courtesy copies here for
21 plaintiff's counsel as well.

22 THE COURT: All right. So I think we should
23 take this up in the morning.

24 MR. ROBINSON: What time, your Honor?

25 THE COURT: Why don't you be here at 8:30, and
26 we'll talk about how to do it. And you said there were a
27 couple of other things you wanted to take up?

28 MR. WILLIAMS: There are. One relates to, I

1 believe, witness Felix. There's a motion. There was a
2 motion in limine filed relating to Dr. Felix, so we'd
3 like to take that up if we could. That's of the shorter
4 variety, I think.

5 MR. CACHAN: It's two pages or three pages, or
6 something.

7 THE COURT: When was that filed?

8 MR. CACHAN: This afternoon, your Honor.

9 THE COURT: Oh, okay.

10 MR. WILLIAMS: It has to do with whether certain
11 things can be delved into on cross-examination, and, if
12 so, how much.

13 THE COURT: And do you have anything else to
14 take up in the morning?

15 MR. WILSON: I don't think so.

16 MR. CACHAN: We can take that up at the noon
17 hour, actually, tomorrow.

18 MR. SMITH: I think we're okay.

19 MR. ROBINSON: Thank you, your Honor.

20 THE COURT: Okay. See everybody at 8:30.

21 (Whereupon an evening adjournment was taken at
22 4:40 P.M. with the matter to be resumed at
23 8:30 A.M. on August 11, 2017.)

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,
SPECIAL TITLE (RULE 3.55)

JOHNSON & JOHNSON TALCUM
POWDER CASES.

JCCP NO. 4872

REPORTER'S CERTIFICATE

I, CAROLYN GREGOR, CSR 2351, pro tem reporter of
the Superior Court of the State of California, for the
County of Los Angeles, do hereby certify that the
foregoing pages, 3103-3204, comprise a full, true and
correct transcript of the proceedings and testimony taken
in the above-entitled cause on August 10, 2017.

Dated this 10th day of August, 2017.

CAROLYN GREGOR, CSR 2351
OFFICIAL PRO TEMPORE REPORTER

Exhibit 122

August 11, 2017

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,)
SPECIAL TITLE (RULE 3.55))
) JCCP NO. 4872
)
JOHNSON & JOHNSON TALCUM)
POWDER CASES,)
_____)

MORNING SESSION
REPORTER'S DAILY TRANSCRIPT OF PROCEEDINGS
AUGUST 11, 2017

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Certificate No. 4497
Court Reporter Pro Tempore

August 11, 2017

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August 11, 2017

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1 CASE NUMBER: JCCP 4872
2 CASE NAME: JOHNSON & JOHNSON
3 TALCUM POWDER CASES
4 LOS ANGELES, CALIFORNIA AUGUST 11, 2017
5 DEPARTMENT 307 HON. MAREN E. NELSON
6 APPEARANCES: (AS HERETOFORE NOTED.)
7 REPORTER: PAMELA COTTEN,
8 CSR NO. 4497
9 TIME: 8:48 A.M.

10 MORNING SESSION

11 (The following proceedings were
12 held outside the presence of the jury:)

13 THE COURT: Good morning, all.

14 MR. WILLIAMS: Good morning, your Honor.

15 MR. ROBINSON: Good morning, your Honor.

16 THE COURT: Good morning.

17 ALL: Good morning, your Honor.

18 THE COURT: On the record outside the presence
19 of the jury. All trial counsel present. Have a seat,
20 folks.

21 On the motion in limine, I read the motion, I
22 read the opposition regarding Dr. Felix. I'm not
23 inclined to grant the motion, but I am a little concerned
24 that we are going to have a long detour into lung cancer,
25 which we don't need to have.

26 MR. ROBINSON: No. It will be very quick, your
27 Honor. We're not going to do that.

28 THE COURT: So let me hear from Mr. Williams and

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1 Mr. Robinson.

2 MR. WILLIAMS: Well, actually, it was Mr. Cachan
3 who was going to do it, your Honor, and he is not here
4 this morning. But we just wanted to avoid that detour
5 that the Court is referencing and try to keep that away
6 from the jury because it's not as important what the
7 matters were about as it is the amount of money that he
8 was paid and that type of thing by our client.

9 So to the extent that there are just certain
10 industries that, if you start jumping there, that's
11 unduly prejudicial, in our view. And so the issue should
12 be related to this case, we think, in the first instance,
13 money is paid by our client, that type of thing.

14 MR. ROBINSON: Your Honor, when these experts
15 choose to work on a case, that's a part of their
16 background and that's -- look what they brought out with
17 Dr. Plunkett, three million dollars, I mean. So that's
18 what they've done. They have an expert who that's what
19 he's worked on before, and it's fair game. We're not
20 going to go on and drag it out. We're just going to
21 bring that point out, your Honor.

22 MR. WILLIAMS: With respect to Dr. Plunkett, you
23 will recall, your Honor, it was the total amount of
24 money. We didn't go into cell phone, using insects to
25 determine whether there's brain activity damage, and that
26 type of thing, and all of the specific opinions that she
27 has given in other cases. We didn't talk about the types
28 of other cases. What we talked about was money.

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1 MR. ROBINSON: They talked about plaintiff
2 lawyers and plaintiffs' cases, your Honor.

3 The important thing is this, is that this is
4 what Dr. --

5 MR. WILLIAMS: Felix.

6 THE COURT: Felix.

7 MR. ROBINSON: What he chose to work on. He has
8 worked on those cases.

9 THE COURT: I don't have a problem with that,
10 but I am concerned that if we are going to start getting
11 into what his opinions were in other cases --

12 MR. ROBINSON: No.

13 MR. SMITH: No.

14 THE COURT: -- then we're going to be down a
15 long detour about cancer that we don't need to go down.

16 MR. ROBINSON: We're not, your Honor.

17 MR. WILLIAMS: And let me be clear, your Honor.
18 Plaintiff/defense, that's absolutely fair game. The
19 ratio of plaintiff to defense, absolutely. But to talk
20 about -- to bring up tobacco and say that you've done
21 stuff in tobacco and to say that you've done stuff on
22 asbestos cases, we just think that that's inappropriate.

23 MR. ROBINSON: We've agreed no asbestos, but we
24 are not going to agree to other cases, your Honor.

25 THE COURT: I'm not going to grant the motion,
26 but I am going to ask plaintiff's counsel to be mindful
27 about not going down the road of what opinions did he
28 give, why did he give it. Otherwise we are going to be

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1 in mini trials on these other cases because we will be
2 hearing all about them.

3 MR. SMITH: Yes, your Honor.

4 THE COURT: I know where this will go.

5 MR. SMITH: Yes, your Honor.

6 THE COURT: All right. On the subject of the
7 motion for nonsuit, what does the plaintiff want to do in
8 terms of a schedule?

9 MR. ROBINSON: Your Honor, I did -- Scot, you
10 want to talk?

11 MR. WILSON: Your Honor, the motions are not as
12 lengthy as maybe we thought. I think one is about 30
13 pages, the others are about five and six.

14 If the Court wants written-out positions, we can
15 submit those. We would prefer to submit those as soon as
16 possible and have the motions argued as soon as possible,
17 but it is totally up to the Court's schedule.

18 THE COURT: If you can file written oppositions
19 today, I'll rule on them on Monday. That would probably
20 be the simplest thing to do.

21 MR. WILSON: I think we can do that, your Honor.
22 Obviously -- the one concern that I have, usually as
23 plaintiffs' lawyers, we get sometimes an oral motion for
24 nonsuit; sometimes we get a motion in writing. Typically
25 we don't do a written opposition.

26 THE COURT: You're not required to. I'm just
27 saying if you want to do one --

28 MR. WILSON: We will do one. The only concern

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1 that I have -- I mean, obviously, I think a lot of time
2 and effort went into citing the record. We will do our
3 best to provide citations with the understanding that,
4 given the very short time frame, we are not citing every
5 little bit and piece of testimony, but we will try our
6 best.

7 THE COURT: All right.

8 MR. ROBINSON: Your Honor, can we have until
9 Saturday? I do think that Mr. Wilson is here today --

10 THE COURT: You can have until Saturday.

11 MR. WILSON: Thank you, your Honor.

12 MR. ROBINSON: Thank you.

13 THE COURT: Just put it up on Case Anywhere so I
14 know that it's there. And it doesn't -- it doesn't need
15 to be elaborate. The law is very straightforward on this
16 issue. We needn't brief the law much. But if you want
17 to cite to certain evidence you think is important for
18 the Court to consider, that's what you need to do. And
19 you can do that in writing or orally. But I'll hear this
20 motion on Monday.

21 MR. WILSON: Thank you, your Honor.

22 MS. ZUKIN: Your Honor, we do have an issue
23 regarding exhibits and objections to our exhibits that we
24 thought were going to be coming in. So we just want to
25 know when to carve out time to deal with that.

26 THE COURT: What are -- we can do that right
27 now.

28 MS. ZUKIN: Mr. Wilson is ready.

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1 MR. WILSON: So we had a very productive
2 discussion with Mr. Webb yesterday. There's basically
3 four categories -- Jeff, do you mind putting up on the
4 screen --

5 THE COURT: Mr. Webb, is this your issue?
6 Because if so, please come forward.

7 MR. WILSON: For all the days and all the
8 different stipulations for each day, at this point we
9 have basically four categories of remaining items that I
10 don't even want to say are disputed but are areas where
11 we do need the Court to weigh in.

12 One relates to the photographs and images of the
13 talc in the tissue that Dr. Godleski took. We think
14 because a sufficient foundation was laid that he actually
15 took those photographs, looking at them himself on the
16 microscope, that those should be admitted, not just
17 identified.

18 We agree -- everybody agrees, nobody wants the
19 Court to take custody of the actual physical bottles, but
20 the photos of the bottles of talc, both Johnson & Johnson
21 as well as the bottles that we took -- that we showed
22 that have a warning as well as the bottles that Johnson &
23 Johnson introduced that do not have a warning, that the
24 photos of the bottles should be admitted, not just
25 identified.

26 There's an issue regarding certain scientific
27 papers and websites. For example, the Pycnogenol Horphag
28 Research advertisement, the NCI websites, all these

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1 different websites, we previously talked about how those
2 under 721(b) would be identified but not admitted.
3 Defendants' counsel would like some of those to be
4 admitted, ironically, taking the position because they
5 are just websites and not scientific publications. We
6 think those should be identified only.

7 Finally, there are specific portions of the
8 trial transcript where counsel read testimony from the
9 deposition for purposes of impeachment that they want to
10 have admitted. Traditionally, your Honor, I think
11 there's a rule on point, but no portion of the transcript
12 goes back to the jury. It is to be read back upon
13 request only.

14 So those are the categories basically, and they
15 can be identified later in specificity.

16 MR. WILLIAMS: Thank you, your Honor. I'm going
17 to handle this one.

18 THE COURT: Okay.

19 MR. WILLIAMS: With respect to the first
20 category on Dr. Godleski, I mentioned this yesterday.
21 Our position is that those are demonstrative exhibits.
22 They are the images that we used during his direct
23 examination of Dr. Godleski. He was asked by both sides
24 about it.

25 Our view is they are not exhibits that should be
26 admitted and, therefore, that should go back to the jury.
27 They are used for demonstrative purposes.

28 THE COURT: But they are a part and parcel of

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1 his report; correct?

2 MR. ROBINSON: Yes, your Honor.

3 MS. ZUKIN: Yes, your Honor.

4 MR. WILLIAMS: Oh, yes, absolutely. But there
5 are a lot of things that -- the reports don't go back,
6 the reports themselves are hearsay, the photographs are
7 hearsay. They are demonstratives that are used for the
8 benefit of the jury.

9 THE COURT: Well, the photographs actually I
10 don't think are hearsay. The -- I mean, they are like
11 any other photograph. If you lay a sufficient foundation
12 to admit them, they can come in. They are no different
13 than the photos of Ms. Echeverria or lots of other
14 photographs that have been admitted in millions of other
15 cases. The only -- they are just not hearsay.

16 So the question is, are they -- if we are not
17 admitting the report, should we admit the photos anyway?

18 MR. WILLIAMS: That's what we think the issue
19 is, your Honor.

20 MR. WILSON: On that point, your Honor, we agree
21 that the report doesn't go back, the report in its total,
22 but these were Exhibits 39A, B, and C. They were
23 segregated from the report, and it was made clear in the
24 testimony that these were photos that he took. It's a
25 lot like an image of an x-ray.

26 THE COURT: Right.

27 MR. WILSON: So I think a sufficient foundation
28 was laid.

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1 MR. WILLIAMS: Then at a minimum, your Honor, we
2 believe that the headings that were used when
3 Dr. Godleski was on there should be taken off.

4 MR. ROBINSON: We agree, your Honor.

5 MR. SMITH: We agree.

6 MR. WILLIAMS: The arrows that were pointed out
7 that were embedded in the photograph.

8 THE COURT: Let me stop you a minute. Do you
9 have clean copies of them without the arrows?

10 MR. ROBINSON: Your Honor, the arrows were -- he
11 was in deposition, and Mr. Klatt asked him to identify
12 the macrophages with arrows. And the arrows -- is that
13 what you --

14 THE COURT: That's what we are talking about.

15 MR. ROBINSON: No, those arrows were actually
16 done under sworn testimony, under oath, where he was
17 marking where, in his opinion, there was macrophages.

18 THE COURT: That's the demonstrative part of it.

19 MR. WILLIAMS: Right. That's not in the report.

20 THE COURT: So if you have clean copies, they
21 are the ones that come right out of his --

22 MR. ROBINSON: His report.

23 THE COURT: -- his report, that would be fine.

24 MR. ROBINSON: Could we use, obviously, the
25 arrows in final argument --

26 THE COURT: You can use the arrows in final
27 argument, sure.

28 MR. WILLIAMS: No objection to that, your Honor.

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1 On the second category, we have no objection to
2 the photographs of the bottles for both sides coming into
3 evidence.

4 THE COURT: Okay.

5 MR. WILLIAMS: On the third issue on -- there's
6 a distinction between scientific papers and certain
7 websites. With respect to the scientific papers, those
8 can be used for demonstrative purposes. We believe they
9 should be --

10 THE COURT: Hang on a second.

11 MR. WILLIAMS: -- potentially used in closing
12 argument as demonstratives, but that the scientific
13 reports should not come in.

14 But there's a difference between that and
15 certain of the websites. The websites that we argue
16 should come into evidence are the ones relating to
17 governmental websites as to which the Court can take
18 judicial notice. And we can provide briefing on that,
19 your Honor, if there's any issue.

20 But with respect to, for example, the NCI
21 website or Center for Disease Control website, the case
22 law is fairly clear on that -- and, again, we can provide
23 that to the Court -- that those matters are things as to
24 which the Court may take judicial notice of the content
25 of those sites.

26 That's very different from the Pycnogenol
27 website. We would not seek to have the Pycnogenol
28 website admitted into evidence. That was a demonstrative

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1 used through Dr. Plunkett to make a point. That's a
2 different thing.

3 So there's a difference between scientific
4 papers, certain governmental websites as to which
5 foundation can be laid, and the Pycnogenol ad. The ad
6 and the scientific papers themselves should not come in.
7 The website shouldn't come in.

8 MR. SMITH: Your Honor, we have clearly
9 established that the NCI website was not an official
10 statement, the NCI or the National Institutes of Health.
11 It was by those whatever, six, seven, eight people
12 independent. So it's not -- you can't take judicial
13 notice of something that's not an official statement by
14 the NCI.

15 THE COURT: So first of all, the scientific
16 papers do not come into evidence. 721(b)(3), the last
17 paragraph, is clear on this. If admitted, relevant
18 portions of the publication may be read into evidence but
19 may not be received as exhibits.

20 MR. SMITH: Sure.

21 MR. WILLIAMS: We are not seeking that, your
22 Honor.

23 THE COURT: All right. That's number one.

24 On the websites, if they are governmental
25 websites, FDA, for example, the Court can probably take
26 judicial notice of it. But I agree with counsel for the
27 plaintiff, the CIR is not a governmental website.

28 MR. WILLIAMS: Oh, no. CIR, we are not claiming

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1 that that -- I thought we were just talking about the NCI
2 website, actually, which is a different website.

3 THE COURT: Well, NCI -- the NCI website -- NCI
4 is part of DHHS.

5 MR. SMITH: And the National Institutes of
6 Health.

7 THE COURT: Right. I think the Court can take
8 judicial notice of the website. The fact that it says
9 that the -- I can't remember exactly what the language
10 is, but it's part of a governmental website.

11 MR. ROBINSON: Your Honor, can Mr. Wilson --

12 THE COURT: I appreciate there's a disclaimer of
13 some part of it, but it's part of a governmental website.

14 MR. WILSON: Very briefly, your Honor.

15 With respect to judicial notice, if we look at
16 Evidence Code 452(h), with something like this, we are
17 talking about judicial notice that is permissive.

18 And here with respect to a website, albeit a
19 governmental one, judicial notice to the extent it's
20 appropriate would be as to the existence of the document
21 but not for purpose of its truth.

22 And with respect to the existence, that gets
23 over an authentication hurdle; it doesn't get over the
24 hearsay hurdle. The document was used totally only as
25 cross-examination. It's clearly hearsay. The witness
26 never authenticated it, never established.

27 It was cross-examined. The vehicle for --
28 pursuant to which cross-examination was permitted was the

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1 witness was asked, like, you would agree that something
2 on the NCI website was a reliable authority. So it was
3 clearly trying to be invoked pursuant to 721(b).

4 To now say, well, this is different than 721(b),
5 after the witness is only cross-examined on the document
6 under 721(b), is unfair.

7 I think judicial notice is fine as to the
8 existence but not for purposes of truth. It should not
9 be an admitted exhibit.

10 THE COURT: That's probably right. Let me hear
11 from you.

12 MR. WILLIAMS: Two different issues, your Honor.

13 721(b) is for purposes of putting it in front of
14 that particular witness trying to establish foundation
15 that the document could be discussed with that individual
16 witness. It's a totally different analysis than whether
17 or not the court may take judicial notice of the
18 document.

19 We respectfully request the ability to brief it
20 because there are cases directly on point for websites
21 almost identical to this. And so it's two different
22 things.

23 THE COURT: I think the question, though, is
24 this: The Court can take judicial notice of the fact of
25 the website. The question is whether the Court can take
26 judicial notice of the statements in the website.

27 This is much like we are regularly asked to take
28 judicial notice of court files. We can take judicial

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1 notice of the pleading but not of the facts that are
2 stated in the pleading.

3 MR. WILLIAMS: If I may, your Honor. Here is
4 the legal distinction, as I understand it, from the cases
5 we saw. You are quite correct that the statements
6 contained on the website do not come in for the truth of
7 those statements that, in fact, there's inadequate
8 evidence related to talc. No, that's not what it is.

9 But the fact that that governmental website says
10 that, that has meaning in this case. It has meaning in
11 terms of the state of mind of our client, it has meaning
12 in terms of reasonableness of their actions, et cetera.

13 So we are not asking the Court to command the
14 jury that this is truth. That's a very different thing.
15 But -- and the examples that we can give you and the
16 cases make that very point.

17 THE COURT: It's a subtle distinction.

18 MR. WILSON: Whether the website says it is a
19 risk factor or says it is not a risk factor, the document
20 is still being offered for its truth and it's being
21 offered for showing the absence of the statement.

22 THE COURT: But the problem that Mr. Williams is
23 identifying is this: Plaintiff is asserting a theory
24 that the defendants had an obligation to warn, that there
25 was sufficient information in the community that they
26 should warn. The fact that a government agency thinks
27 there is not sufficient evidence goes properly to their
28 state of mind.

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1 MR. WILSON: Your Honor, we have heard no
2 evidence for -- any Johnson & Johnson witness saying that
3 the reason why we didn't provide a warning is because the
4 NCI said that talc was not a risk factor.

5 I think to -- and as Mr. Smith notes, for the
6 vast majority of the time, up until just about a month
7 before trial, talc was listed as a risk factor.

8 THE COURT: There's an argument to the jury
9 about that.

10 MR. WILSON: I think the Court's original
11 analogy pointing to this type of evidence as being like a
12 request for judicial notice as to the truth of what is
13 stated in a court record is directly on point.

14 THE COURT: Well, if counsel has cases you want
15 me to look at, I'm happy to look at them. So if you can
16 either file a very, very short brief --

17 MR. WILLIAMS: We will.

18 THE COURT: -- that consists only, perhaps, of
19 the names of cases.

20 MR. WILLIAMS: That's right, your Honor.

21 Finally, on the portions of the transcripts,
22 here is what we are saying there. Prior inconsistent
23 statements come in for the truth of the matter asserted.

24 Our point was to merely keep track of all of the
25 times that there was impeachment read into the record
26 that consisted of prior inconsistent statements under
27 oath. We do not seek to have those portions to go back
28 to the jury.

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1 What we were simply trying to do was to keep
2 track for the Court, counsel, the parties of all of those
3 instances, because if there were to be a request for a
4 readback, they could easily be identified and they could
5 be read back to the jury. That's all that we were doing
6 by putting those -- chronicling those on the exhibit
7 list.

8 So, to be clear, we're not claiming that they
9 should be copied and go back as exhibits.

10 MR. WILSON: If that's what they want to do, I
11 think they can make the point in closing argument and
12 they can point to the portion of the transcript. If the
13 jury thinks it's significant, they can write that down
14 and ask for a readback if they are interested.

15 THE COURT: Right. I just don't think the
16 transcripts themselves go back to the jury.

17 MR. WILSON: Exactly, your Honor.

18 MR. ROBINSON: Your Honor, I have one question
19 about what we just discussed raises. So in final
20 argument, both sides would be able to cite from the
21 transcript.

22 THE COURT: Sure.

23 MR. ROBINSON: That's fine.

24 MR. SMITH: In closing statement we can put
25 trial transcript testimony up?

26 THE COURT: Yeah.

27 MR. SMITH: Okay.

28 THE COURT: Let me ask an unrelated question but

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1 perhaps related. Have counsel talked about what you want
2 to do on the negligence per se instruction? I know when
3 we started there was an agreement not to reference the
4 FDA issue in opening. Has there been further discussion
5 about that? Because that in part bears on this nonsuit
6 motion.

7 MR. ROBINSON: Mr. Wilson has a brief on that,
8 your Honor.

9 MR. WILSON: So, your Honor, we had proposed a
10 CACI 418 instruction modeled after exactly the way the
11 framework of the CACI 418 instruction is set forth in the
12 Judicial Council jury instructions. Based upon 740.1(a),
13 we believe that it would read something to the effect of
14 "Title 21, Section 740.1(a), the Code of Federal
15 Regulations states" -- and then verbatim provide that
16 regulation.

17 And then this is -- and again, we maybe have to
18 modify this based upon the fact we have two defendants,
19 but the second element, we never really talked about this
20 when we previously talked about negligence per se or
21 740.1(a).

22 There was an argument about how this instruction
23 shouldn't be given because it doesn't have a causation
24 component, but it does, and it is that the violation has
25 to be a substantial factor in bringing about the harm
26 suffered by the plaintiff. Then you must find the
27 defendant was negligent unless you find the violation was
28 excused.

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1 It goes on to say that this is -- if you don't
2 find negligence under this theory, you have to still look
3 at the other instructions.

4 THE COURT: Here's the problem with this
5 instruction. Everyone tells me that it's reversible
6 error per se not to follow CACI. Let me remind you that
7 the instructions for CACI say that they should be
8 modified appropriately for a case.

9 The problem with the negligence per se
10 instruction in this context is the substantial factor
11 language because to read the instruction as it is, first
12 of all, the jury might reach the conclusion that there
13 was no warning, Ms. Echeverria used the product, done.
14 There is liability. That's not the law.

15 MR. WILSON: I think, your Honor, the other
16 instructions that we have make it clear that that would
17 not be sufficient for the imposition of liability so that
18 the failure to provide the warning is not enough.

19 THE COURT: Not only is it not enough, but she
20 has to prove that the cancer --

21 MR. WILSON: Correct, your Honor. We have the
22 other instructions --

23 THE COURT: Right. But you didn't --

24 MR. ROBINSON: More probable than not could
25 change the concern about substantial factor.

26 THE COURT: But the problem is that the
27 language -- the violation was a substantial factor is
28 really not sufficient in this context because it's not

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1 simply the violation. There also has to be proof that
2 the cancer is caused by the product.

3 MR. SMITH: Sure.

4 MR. WILSON: But rather than just saying in
5 light of that modification, that is appropriate, let's
6 not give this instruction at all; let's modify it in a
7 way that I think addresses the Court's concern.

8 THE COURT: Well, you can take a stab at that.
9 But that's the big problem here, I think.

10 MR. WILSON: Okay. Fair enough. We agree.

11 MR. WILLIAMS: Your Honor, we have discussed
12 this several times.

13 THE COURT: We have been around about it.

14 MR. WILLIAMS: And I just wanted to remind the
15 Court where we were. And so I thought that this might
16 come up, and so I have a transcript from that which I
17 think crystalizes the issue. If I may.

18 First of all -- and this is -- for the record,
19 this is the transcript from July 26, 2017. And this is
20 the comment of the Court.

21 "The law is clear, but there is a
22 question of how it's going to be applied
23 here. You can talk to counsel for a
24 second. If he wants to not mention
25 anything about the FDA regulation in his
26 opening statement, and we don't have to
27 think some more about this, that's okay.

28 "But, otherwise, I think the

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1 defense has the better of the argument
2 here, that the -- that, first of all,
3 it's really not dicta in Valentine, in
4 my view, and it's all a part of what the
5 duty to warn is.

6 "So if you would rather not talk
7 about 740.1 in your opening statement, I
8 understand that. You've made your
9 record. I understand the problem. I
10 think on this -- this set of facts, and
11 particularly with giving this 'may' --
12 giving the 'may' language in 740.1, it
13 has to be crystal clear to the jury that
14 'may' doesn't mean 'possibly.'"

15 THE COURT: That's the second problem with the
16 instruction.

17 MR. WILLIAMS: And there was an additional
18 discussion, and the Court made clear -- this at page 617,
19 line 4:

20 "Counsel, you have already said it
21 three times."

22 Addressing plaintiff's counsel.

23 "I appreciate what you say. I
24 understand the problem. But I think if
25 you're going to put 740.1 at issue in
26 this case, the jury has to have it --
27 has to have had it made crystal clear to
28 them that 'may' does not mean

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1 'possibly.' Valentine addresses that
2 directly."

3 And that followed, your Honor, my argument that
4 it wasn't just opening statement; it was putting it at
5 issue in the case.

6 You continued and said, "You have made your
7 record."

8 But then Mr. Cachan sought clarification about
9 whether the issue was coming in.

10 "And just to clarify, your Honor,
11 this is the issue coming out of the
12 case. We're not talking about it. It's
13 not going to be in the opening. And
14 we're going to hear a little bit later
15 about some mysterious federal regulation
16 unstated, or 740.1, because, if that's
17 the issue, it's different."

18 And the Court said:

19 "The time is now. The plaintiff
20 has to elect whether they want to" --

21 Then Mr. Robinson spoke up. He asked for 1222
22 and extra language from Valentine. And then the Court
23 said:

24 "Here is what counsel is asking,
25 and this is my question as well: It's
26 not just a question that it's not going
27 to be in opening statement here; there
28 is not going to be any evidence in this

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1 trial on 740.1. Yes or no?"

2 "Mr. Robinson: We'll do it, your Honor.

3 "We'll do what?

4 "We won't go to 740.1, but no

5 Valentine."

6 So that was the issue. The issue was clear that

7 740.1 --

8 MR. ROBINSON: No.

9 MR. WILLIAMS: May I finish, your Honor?

10 THE COURT: Just a minute. Let counsel finish,
11 and then you can respond.

12 MR. WILLIAMS: That 740.1 wasn't going to come
13 in. And so the Court then asked:

14 "So with that in mind, did counsel
15 want me to preinstruct the jury at all?"

16 Mr. Robinson said:

17 "I don't see any reason."

18 Mr. Cachan said:

19 "We don't either, but with this
20 clarification, your Honor, which is we
21 want to make certain that the fact 740.1
22 is no longer in the case doesn't mean
23 that all of a sudden we're prohibited
24 from bringing up the FDA letter,
25 understanding we're not talking about
26 740.1, but the FDA letter should not be
27 affected."

28 And we asked for clarification. The Court then

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1 said:

2 "Right. That's a whole different
3 issue, but we don't have to give that
4 this morning. So if you want to do
5 that, I think it's okay. That's a fair
6 inference from your -- the letter will
7 come in, but I think counsel is entitled
8 to argue that the fact that the FDA does
9 not require a warning because there
10 wasn't inclusive" -- that may have been
11 "conclusive" -- "proof isn't the
12 standard in the state."

13 So our point is 740.1, the statute, the per se
14 instruction that counsel and Mr. Wilson just put up,
15 should not be used. There was that long argument. And
16 you'll remember Mr. Cachan saying it either is the same
17 standard as California or it isn't. If it's the same
18 standard, then it's confusing, for the reasons the Court
19 has said. If it's a different standard, 740.1 cannot
20 change the law. That was the thing that we talked about
21 again and again.

22 So I'm doing my best to channel Mr. Cachan, but
23 the point is that the instruction that they're requesting
24 should not be given, in our view. They made a choice at
25 the beginning of the case whether it was coming in or
26 not. And they should have to live with that.

27 THE COURT: Mr. Wilson.

28 MR. WILSON: Thank you, your Honor.

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1 Everything that counsel just talked about came
2 up in the context of the preinstructions. We were
3 talking about what we were going to preinstruct the jury
4 about. We wanted 418. We wanted 740.1(a). They wanted
5 Valentine and the modified CACI 1220. They got -- what
6 Mr. Robinson was talking about was a tradeoff. We won't
7 ask for the 740.1 preinstruction if they don't get their
8 modified Valentine 1222. They got their way. What they
9 really want now is to have their cake and eat it too.
10 That's what's going on. We never gave up the right to
11 instruct the jury at a later time on 740.1(a).

12 What the Court, I think -- you know, we were
13 talking about also the Cooper instruction that the Court,
14 I think, was weaving into how to appropriately give
15 740.1(a) in this context, with that Cooper instruction
16 that the Court came up with. That is an appropriate
17 compromise here. But to say that we just forfeited the
18 right to ever have the jury instruction on 740.1(a) or to
19 introduce any evidence, that's not what happened. We
20 were talking about preinstructions. We wanted some; they
21 wanted some. They got their way. They got the ones that
22 they wanted; we got nothing that we wanted.

23 THE COURT: Well, you could have had a
24 preinstruction, but you didn't want the preinstruction
25 that I was going to give.

26 MR. WILSON: So we weren't talking about
27 preinstructions at that time, your Honor.

28 MR. WILLIAMS: Respectfully, your Honor, what I

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1 just showed the Court was the Court saying that the time
2 was now for the plaintiff to make that decision. That's
3 what the Court did. They didn't want to have the
4 preinstruction. When faced with the decision about
5 whether to use 740.1 and get an instruction for the jury
6 or not, they chose not to do that. The Court made
7 crystal clear three other places that, if they were to
8 make that choice at that time, the Court was going to
9 give the extra Valentine language in the instruction.
10 They didn't want that. They made that choice.

11 What they're asking for now is to try to -- I
12 guess, the passage of time and the fading of memory,
13 they're trying to now say that 740.1 is front and center
14 in the case. That's not what happened. The Court told
15 them that they had to make a decision. The decision was
16 made. The question at the end of the discussion was
17 whether or not 740.1 is coming in the case or not, not
18 just opening statement.

19 MR. WILSON: Your Honor, we were talking about
20 preinstructions. They got the preinstruction that they
21 wanted. We didn't -- 740.1 wasn't preinstructed. There
22 was never an agreement that it was never going to be
23 instructed at the conclusion of the case. To call it a
24 centerpiece of the case is not accurate. It is part of
25 the claims. It is part of the instructions. It's part
26 of the evidence in the case. We're going to hear about
27 it shortly from the witness that's on the stand right
28 now.

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1 And, you know, we would just ask that we be
2 allowed to permit what we believe is an appropriate set
3 of final jury instructions, including the very CACI -- or
4 the 740.1 instruction, as well as maybe the Cooper issue,
5 to address how to appropriately put this before the jury.
6 To wipe it out when we were clearly having a discussion
7 where we were proposing a tradeoff, "Look, we won't go to
8 740.1 if you don't do this modified 1222, and we won't
9 talk about it in opening." To say that that's now barred
10 us from including it in the final instructions is not
11 accurate, and it's just not what happened.

12 MR. WILLIAMS: May I?

13 MR. WILSON: Sure.

14 MR. WILLIAMS: One more time, your Honor. It is
15 what happened. The transcript doesn't lie. This is
16 page 620.

17 "The Court: Mr. Robinson, here is
18 what counsel is asking and this is my
19 question as well: It's not just a
20 question that it's not going to be in
21 opening statement here. There is not
22 going to be any evidence in this trial
23 on 740.1. Yes or no?

24 "Okay, your Honor. We'll do it,
25 your Honor.

26 "You'll do what?

27 "We won't go to 740.1, but no
28 Valentine."

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1 The choice was made at that time that 740.1 was
2 in or out of the case. Counsel just mentioned -- this
3 shows exactly what they planned. We're not going to talk
4 about 740.1 with Dr. Andersen. Counsel and Mr. Wilson
5 just mentioned a minute ago that they plan to try to do
6 740.1 with Dr. Andersen.

7 MR. ROBINSON: Your Honor --

8 MR. WILLIAMS: That's not in the case. The
9 choice was made at that time. The Court gave them a
10 choice. It was about whether it's coming into the case.
11 It could not be clearer.

12 MR. ROBINSON: Your Honor, later, the Court --
13 whatever happened here, the Court put the Valentine
14 instruction in. So all bets were off.

15 THE COURT: The Court put the Valentine
16 instruction in because Mr. Smith --

17 MR. ROBINSON: Yes, that was the condition.

18 THE COURT: That was different. Mr. Smith made
19 reference in the opening statement, if I recall
20 correctly, to separate -- that causation need not be
21 shown here. That is why they were preinstructed with the
22 Valentine instruction.

23 MR. ROBINSON: Your Honor --

24 THE COURT: That's different.

25 MR. ROBINSON: But, your Honor, what I'm saying
26 is, that's why I -- whatever the reason was, Valentine
27 was put in. So I'm just saying that that was the only
28 reason I was saying in my opening statement I wasn't

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1 going to mention 740.1. The bottom line is 740.1 is the
2 law -- federal law on this case, your Honor. And,
3 basically, Valentine was read in. So I think 740.1 is
4 what should be given to the jury.

5 THE COURT: All right. So my recollection has
6 been refreshed about this point. Thank you.

7 MR. WILSON: Your Honor -- I'm sorry. This was
8 a discussion about a tradeoff.

9 THE COURT: Okay. Excuse me, Counsel.

10 MR. WILSON: I'm sorry.

11 THE COURT: At the very beginning of this, there
12 was a discussion about whether 740.1 was going to be in
13 the case or not in the case. And if it was -- if it was,
14 what instruction we were going to give the jury at the
15 beginning so that they would understand the context of
16 740.1 and not be under the misimpression that the word
17 "may," as used in this statute, was mandatory or wiped
18 out any "likely/more probably than not" requirement and
19 causation still had to be proven.

20 Plaintiff elected not to go with 740.1. I read
21 the Valentine instruction later as a curative instruction
22 because of the statements that were made in opening
23 statement.

24 Defense counsel is correct. I'm not going to
25 instruct on 740.1. You elected out of it.

26 MR. WILLIAMS: For clarity, your Honor, it would
27 not be appropriate for Mr. Smith on cross-examination to
28 put 740.1 in front of Dr. Andersen when I'm not going

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1 there at all, not raising that at all. It would be
2 inappropriate. 740.1 should be out of the case, and the
3 jury should not be confused on the issue.

4 MR. SMITH: Your Honor, it's in his report. He
5 relies on it in the four corners of his report. It's not
6 like Dr. Plunkett. I understand why the judge said --
7 Dr. Plunkett didn't work at the FDA, didn't have specific
8 knowledge. He says he knew everything and worked in
9 every department of the FDA. He has 740.1(a) quoted in
10 his report, and the basis of his opinions through his
11 deposition are in the four corners of his report. That
12 is a different story.

13 They elected to bring this witness. They didn't
14 have to bring him. But if we're talking about the
15 opinions -- if I've been stuck to the four corners of my
16 experts' reports, what's good for me ought to be good for
17 them. And they elected to bring this witness, and he
18 relies on it and quotes it in his report.

19 MR. WILLIAMS: Your Honor, he is giving no
20 opinions regarding 740.1. We have been -- he's not
21 giving any opinions regarding FDA. We established that
22 he worked at the FDA. The opinions that he is giving
23 relate to the CIR and they relate to the safety of talc.
24 We are not giving that opinion.

25 The reason that it was in his report is that we
26 knew that they -- specifically, Dr. Plunkett -- had
27 intended to give all kinds of opinions concerning 740.1.
28 In his report, Dr. Andersen says that he's giving

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1 responsive opinions.

2 THE COURT: May I see the report?

3 MR. WILLIAMS: Sure.

4 MR. SMITH: Here you go, your Honor. May I
5 approach?

6 THE COURT: I don't have a notebook -- let me
7 just -- do you have a complete notebook for Dr. Andersen
8 that the Court can have? If it's in the notebook, I'll
9 just get it. Is the report in there?

10 MR. WILLIAMS: It is.

11 THE COURT: Okay.

12 MR. WILLIAMS: Or I believe it is.

13 MR. SMITH: Further, your Honor, I just want to
14 make another point on this while you're reading to give
15 some context. He says that all his reliance materials
16 for the basis of his opinion are in his report. He went
17 and read Mr. Steinberg and Dr. Plunkett's prior
18 deposition testimony and report where it lays out
19 740.1(a), and then he cites it in his report and
20 interprets 740.1(a).

21 I'm not going to ask him to interpret a statute.
22 You said that invades the province of the jury. But to
23 say somehow that 740.1(a) isn't in here when it's both in
24 Mr. Steinberg's deposition and report, Dr. Plunkett's
25 deposition report -- which he says he relies on -- and
26 then cited and quoted in the four corners of his report,
27 is ridiculous.

28 And, you know, again -- I will say again, your

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1 Honor, they did not have to call this witness and put
2 this at issue. Just because they didn't bring it up on
3 cross doesn't erase it that he's relied on it in his
4 reference materials and it's cited in his report.

5 MR. WILLIAMS: Your Honor, may I walk you
6 through this?

7 THE COURT: Sure.

8 MR. WILLIAMS: First of all, at the bottom of
9 page 3, if you have D25 in front of you, your Honor.

10 THE COURT: I do.

11 MR. WILLIAMS: At the bottom of page 3, it says:

12 "I anticipate testifying at trial
13 regarding the assessment of the safety
14 of talc as used in cosmetics, the issue
15 of the use of scientific data in making
16 safety assessments in general and the
17 procedures used by the CIR in
18 particular, and the role of
19 manufacturers in such safety
20 assessments. I also anticipate
21 responding to the opinions and testimony
22 offered by the plaintiff's experts in
23 this case."

24 If you then turn back to the later portion where
25 it references Dr. Plunkett and Mr. Steinberg, and that's
26 on page --

27 THE COURT: Can you tell me where that is,
28 please?

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1 MR. WILLIAMS: If you'll bear with me.
2 Dr. Plunkett is on page 16 of D25, paragraph 10. What
3 the doctor did, Dr. Andersen, was he went through the CIR
4 report. He then says that he is going to be responsive
5 to Steinberg and Plunkett. On paragraph 10 he cites the
6 October 5, 2006, expert report of Dr. Plunkett and all of
7 her statements about 740.1, which you will see on page 17
8 at the top. You'll see it says up there at the top:

9 "It is informative, therefore, that
10 FDA has denied two petitions," et
11 cetera.

12 So, your Honor, this portion was responsive. Of
13 course, Dr. Plunkett, the Court kept that out. So there
14 has been no opinion given by Dr. Plunkett on 740.1.
15 Dr. Andersen was going to respond to those opinions, as
16 we had to have him do, because, in other cases, 740.1 was
17 front and center in the plaintiff's theory. They tried
18 to make it front and center here. The Court disagreed
19 and disallowed Dr. Plunkett's testimony in that regard.

20 After that, we had the colloquy that's up on the
21 board right now, where the Court said, "You have to
22 decide" -- plaintiff's counsel -- "whether this is coming
23 in or it is not." So to simply say that it's in
24 Dr. Andersen's report when it's in his report as a
25 response to potential testimony of the expert on the
26 other side, what were we to do? The plaintiffs intended
27 to make that argument. We had to be in a position to
28 respond.

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1 But that is not the opinions that he has given
2 in this case. We do not intend to elicit it from him.
3 It would turn the rule on its head to simply say that the
4 fact that we put it in our report responding to what
5 their expert planned to do means that it automatically
6 becomes an issue in the case. That is what makes no
7 sense, with all due respect to plaintiff's counsel. It
8 is not simply that the word is in the report. It was
9 there for a reason. It was there to respond to
10 Dr. Plunkett. Dr. Plunkett has not been permitted to
11 make that testimony.

12 THE COURT: Do you want to make your argument
13 about Mr. Steinberg? It's the same, I assume.

14 MR. WILLIAMS: Well, it was the same with
15 Steinberg. They chose not to call him in the case.

16 So either way you look at it, the fact that this
17 is in the report should not obviate everything that we
18 went through, the weeks of argument on 740.1, where the
19 Court made them make a decision.

20 The sequence was, after the Court made them make
21 a decision, they said no, as you can see up on the board,
22 on line 12, on page 620 of the transcript. Mr. Smith
23 then injected it again into opening statement,
24 distinguishing "may" language from causation. The Court,
25 in reaction to that, after having agreed not to give the
26 Valentine instruction, gave the Valentine instruction.

27 So this is of their making; it's not of our
28 making. Now they're trying to inject it in through this

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1 witness again when their expert was prevented from doing
2 it. Ours was simply to be responsive.

3 MR. SMITH: Your Honor, what's good for the
4 goose is good for the gander. I mean, I've had to stay
5 within the four corners of my report. It is cited. It
6 doesn't matter -- he gives an opinion on it.

7 But beyond even that, he said he relies on, for
8 the basis of his opinions, the report of Mr. Steinberg,
9 the deposition of Mr. Steinberg was exclusively
10 mentioned, and Dr. Plunkett's deposition and her report,
11 which continually talked about it. It --

12 THE COURT: Excuse me.

13 MR. SMITH: I'm sorry.

14 THE COURT: Can you tell me where in
15 Dr. Andersen's report he relies on Dr. Steinberg or
16 Dr. Plunkett with respect to his opinions regarding the
17 CIR safety assessment? That's the first part of the
18 report. And if he tells us what his point of view is
19 about that.

20 MR. SMITH: I don't think the CIR report is at
21 issue, your Honor, that we are talking about. I think
22 it's more on page 16 and 17 of his report.

23 THE COURT: Right. But that is, as he makes
24 clear on page 3, rebuttal to the opinions and testimony
25 offered by plaintiff's experts in this case. That's what
26 it says. That's what the report says.

27 So if your -- since Dr. Plunkett didn't talk
28 about the FDA and Dr. Steinberg -- is it Dr. Steinberg?

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1 MR. SMITH: Mr. Steinberg.

2 THE COURT: Mr. Steinberg wasn't called as a
3 witness. There's nothing to rebut. No part of the
4 report really needs to deal with that.

5 MR. SMITH: Okay. Give the defense that.
6 That's fine. But look at Number 2 under page 3, "Other
7 Materials." He went not just as rebuttal to -- he went
8 and said:

9 "Other materials that he's relied
10 on: expert report and deposition of
11 David Steinberg; expert report and
12 deposition of Laura Plunkett; the Hill
13 criteria; the FDA website, which has
14 this on it; consent judgment."

15 He went to the FDA website. It has this 740.1
16 language on it. "Consent judgment involving the people's
17 claim against defendant Glive [phonetic]. Description of
18 clinical trials." So it's on the website he also said he
19 went to besides just rebuttal testimony of Steinberg and
20 Dr. Plunkett.

21 THE COURT: But the information he deals with,
22 the testimony that was anticipated to be given by
23 Dr. Plunkett and Mr. Steinberg, if counsel doesn't bring
24 that out, I don't think it's proper given the scope of
25 plaintiffs.

26 MR. SMITH: Even though he was at the FDA, he's
27 aware of warnings, he said went to the FDA website, he
28 has reliance materials on his report outside

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1 Mr. Steinberg or Dr. Plunkett.

2 THE COURT: The problem, Counsel, is that if he
3 doesn't give an opinion on that issue, there's no -- it's
4 outside the scope of his opinion.

5 MR. SMITH: Well, the defense counsel just filed
6 a pleading to take judicial notice of the 2014 citizen's
7 petition that has it in it.

8 MR. WILLIAMS: Your Honor, these are two totally
9 separate issues. I'm not going to talk about the 2014
10 issue that we just filed the judicial notice on at all
11 with Dr. Andersen.

12 As the Court indicated, and I showed just a few
13 minutes ago, we specifically raised the issue of whether
14 or not 740.1, the fact that that is not coming into the
15 case, would prevent us from putting in the FDA letter.
16 That was this portion of the transcript at page 627 of
17 the transcript on July 26 where Mr. Cachan raised the
18 issue. And the Court said:

19 "That's a whole different issue,
20 but we don't have to go into that this
21 morning. If you want to do that, I
22 think it's okay. That's a fair
23 inference from your -- the letter will
24 come in. But I think counsel is
25 entitled to argue that the fact that the
26 FDA does not require a warning, because
27 there wasn't inclusive proof" -- that
28 might have been "conclusive" -- isn't

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1 the standard in the state."

2 So the point is that the issue of whether or not
3 we separately can put in and have the Court take judicial
4 notice of the fact that the FDA denied a citizen's
5 petition relating to talc, which is a key issue as to our
6 state of mind, as to the state of play we are in talc,
7 that's a different thing from whether or not counsel gets
8 to put 740.1 into the case through a witness where the
9 witness is not giving that testimony.

10 So to respond directly to what counsel said
11 about listing the references, of course the witness has
12 to list all of the references. But the references he was
13 pointing to were references in response to Dr. Plunkett
14 and Mr. Steinberg.

15 MR. SMITH: The reason we didn't go to 740.1(a)
16 with Dr. Plunkett is because we were under the impression
17 the Court was going to read the statute to the jury, and
18 there was no email interpretation, number one.

19 Number two, they want to take judicial notice of
20 an FDA letter that spells out 740.1(a) and (b), but then
21 I'm not able to use it. It makes no sense.

22 THE COURT: If you're going to -- well, I'm
23 going to have to take a look at the letter again. Where
24 is it?

25 MR. WILLIAMS: I don't have a copy on me.

26 MR. SMITH: I've got a copy.

27 MR. WILLIAMS: The letter does not cite 740.1.
28 It uses the language of 740.1, and the writer from the

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1 FDA says that:

2 "Based on the totality of the
3 evidence that's in front of the FDA, we
4 do not believe that a warning is
5 required on this state of evidence with
6 respect to talc."

7 It does not cite -- and I think it's very
8 intentional that they do not cite the regulation. They
9 simply use the language -- borrow the language from the
10 regulation in saying what they are finding.

11 So the Court separated the two issues when we
12 discussed this very same thing, said that the letter does
13 come in -- the letter comes in, but this opinion they're
14 trying to elicit through this witness should not.

15 MR. SMITH: Okay. Maybe I won't say 740.1(a).
16 But if you'll read the second paragraph, they want to
17 take judicial notice of -- read the second full
18 paragraph, your Honor, please.

19 Can't state it any clearer.

20 THE COURT: No, you can't.

21 So here's the problem: The letter that you want
22 the Court to take judicial notice of says the following:

23 "We have carefully considered both
24 of your petitions. We are committed to
25 the protection of the public health and
26 share your interest in reducing the risk
27 of ovarian cancer. Current regulations
28 state that cosmetic products shall bear

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1 a warning statement whenever necessary
2 or appropriate to prevent a health
3 hazard that may be associated with a
4 product. FDA may publish a proposal to
5 establish a regulation prescribing a
6 warning statement on behalf of a
7 petitioner if the petition is supported
8 by adequate scientific basis on
9 reasonable grounds."

10 MR. SMITH: That's 740.1(a) and (b).

11 THE COURT: Okay.

12 "After careful review and
13 consideration of the information stated
14 in your petitions," et cetera --

15 I'm going to skip some of this.

16 -- "FDA did not find that the data
17 submitted presented conclusive evidence
18 of a causal association between the talc
19 use in the perineal area and ovarian
20 cancer. For this reason and additional
21 reasons described below, FDA is denying
22 your petitions."

23 It goes on.

24 If you're going to put the FDA language before
25 the witness -- well, if you're going to ask the Court to
26 take judicial notice of the fact of the letter, that
27 would be one thing; namely, that there is such a letter.
28 The -- but the letter does state what the position of the

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1 FDA is about what the regulations state. So it's
2 conceivable to me, depending on what Dr. Andersen says in
3 his direct, that there will be room to cross him on this.
4 I don't know what he's going to say, but --

5 MR. WILLIAMS: Dr. Andersen is not giving any
6 opinions regarding warnings. He is not giving any
7 opinions regarding regulation. He is not doing any of
8 that. That was going to be responsive to a possible
9 opinion of Dr. Plunkett.

10 As you know, your Honor -- I'm almost done with
11 him. And he has talked about the CIR and only about the
12 CIR. So we're not going to put it in front of him. To
13 permit them to cross-examine him on it would be
14 inappropriate.

15 The only reason for doing it would be to blur
16 the lines between the language, which you will see there
17 is interpreted as causal, and the "may" language from
18 740.1. It's exactly the same thing that plaintiff's
19 counsel has done repeatedly, which is why the Court gave
20 the instruction it did at the beginning.

21 The reason why we're here is because -- and the
22 reason Valentine was given was because plaintiff tried to
23 do precisely that by blurring it. The only reason that
24 counsel would want to put that in front of Dr. Andersen
25 would be to try to blur the line again and to emphasize
26 the "may" language and to try to suggest to the jury that
27 there was some duty to warn because the regulation uses
28 the word "may," which is exactly the vice that the Court

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1 said should not happen because that's not the law that
2 the jury is supposed to be deciding in this case.

3 So, again, they shouldn't be permitted to inject
4 this into the case. That is a different question from
5 taking judicial notice of the denial of the citizen's
6 petition.

7 MR. SMITH: He wants judicial notice of the
8 denial but not what the rest of the language is. This
9 witness has got up and said "I work at the FDA. I was in
10 every department. I'm a labeling expert." He said
11 "labeling expert." And for me to be hamstrung now
12 because he has talked about all his experience -- this is
13 not Dr. Plunkett that didn't work at the FDA, didn't say
14 "I worked in every department, that I worked on labeling,
15 and I'm a labeling expert and know all this information."
16 For me not to say "you don't know the information" or
17 "you don't know about the citizen's petition" or what
18 that language says that they want to take judicial notice
19 of, it defies legal logic.

20 THE COURT: I'm not exactly clear, Mr. Smith, on
21 how you intend to -- what you intend to do here.

22 MR. SMITH: Can we just take it as it goes and
23 see how it goes? I mean --

24 THE COURT: Well, I think we may have to do
25 that. But the problem I see is two-fold. If the witness
26 doesn't testify to any FDA warning anything, all he said
27 is "I used to work for the FDA and worked my way up the
28 ladder in these various positions, including the

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1 labeling," that if you are going to try to cross-examine
2 him on his expertise because he doesn't know about this
3 letter or something, that might be one thing, but --
4 although I have to say I think it's written after he left
5 the FDA --

6 MR. WILLIAMS: True.

7 THE COURT: -- so how he would know about it
8 is --

9 MR. SMITH: Well, he says he stays up with the
10 FDA and talks to his people back all the time.

11 I mean, look, we can take it up as it goes. If
12 I can't lay the foundation to do it, well, then I'm sure
13 there will be an objection and I can't do it.

14 MR. WILLIAMS: Well, now, here's the thing, your
15 Honor, that's not fair, because he's duty-bound to give
16 honest answers.

17 If Mr. Smith is permitted to go down this path
18 and to ask him questions about labeling, his experience
19 with labeling, of course he's going to say that he has
20 experience with labeling. And then Mr. Smith is going to
21 argue that the door has been opened and that he has laid
22 a foundation and go plunging into 740.1. That's not
23 appropriate.

24 THE COURT: Let's see where we go here. But
25 remind the plaintiff's counsel that from what's in the
26 record, you've made this issue on 740.1, you've made your
27 choice. The Court, I think, has been very, very clear
28 that it is not to be suggested in any way to the jury

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1 that this FDA regulation or its use of the word "may" is
2 to be interpreted in a way that precludes causation.

3 MR. SMITH: I agree. I totally agree.

4 MR. WILLIAMS: He agrees each time, your Honor,
5 and then he does exactly the opposite.

6 THE COURT: Mr. Smith, all I can say is that
7 you've heard what I have to say.

8 MR. SMITH: Yes, your Honor. Thank you.

9 MR. ROBINSON: Your Honor, another matter, I
10 think -- in fairness, I think I should be able to make --
11 to clear something up on the record.

12 Originally when we offered Dr. Plunkett to
13 testify regarding 740.1(a), the Court said, "No. I will
14 read 740.1(a) into the record."

15 Now, the defense then wanted Valentine. And so
16 in exchange for no Valentine, I said -- we were talking
17 about opening statement, but I said, no, no 740.1(a).

18 And then -- but what happened is the Court then
19 read Valentine. So now the, you know, the concession
20 that I wanted, no Valentine, was taken away. I think
21 that automatically puts back 740.1(a) into the case.

22 THE COURT: Counsel --

23 MR. ROBINSON: That's why I think it should be a
24 negligence per se issue, your Honor.

25 THE COURT: I disagree with you. The reason the
26 Court read Valentine was because in the opening statement
27 plaintiff's counsel suggested to the jury it would not
28 have to make a causation finding.

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1 Is the jury ready?

2 COURT ASSISTANT: Yes.

3 (The following proceedings were
4 held in open court in the presence of
5 the jury:)

6 THE COURT: Good morning everyone.

7 ALL: Good morning.

8 THE COURT: Everybody doing okay?

9 ALL: Yes.

10 THE COURT: All right. Good morning. Let's
11 have a seat. We have all the jurors here, two
12 alternates, all trial counsel, Dr. Andersen on the stand.

13 Mr. Williams.

14 MR. WILLIAMS: Thank you, your Honor.

15 DR. ALAN ANDERSEN,
16 having been previously sworn, resumed the stand and
17 testified further as follows:

18 DIRECT EXAMINATION (Resumed) (9:47 A.M.)

19 BY MR. WILLIAMS:

20 Q Good morning, Dr. Andersen.

21 A Good morning.

22 MR. WILLIAMS: Good morning, everybody.

23 ALL: Good morning.

24 BY MR. WILLIAMS:

25 Q Dr. Andersen, at the end of the day -- is the
26 mic working?

27 THE COURT: I don't think so.

28 MR. WILLIAMS: I think it is.

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1 BY MR. WILLIAMS:

2 Q Dr. Andersen, at the end of the day yesterday,
3 we ended by discussing one of the studies focusing in on
4 the Hamilton study, which was one of the studies cited by
5 the Cosmetic Ingredient Review.

6 Do you remember that?

7 A Yes.

8 Q I don't want to take the time to go into the
9 specifics of the following studies, but I do want to just
10 mention them and ask you this question: Did the Cosmetic
11 Ingredient Review have available to it and review the
12 scientific study known as Buz'Zard, which is
13 Exhibit L131, when it reached its conclusions as set
14 forth in the CIR report?

15 A Yes, it did.

16 Q It did?

17 COURT ASSISTANT: Excuse me, Counsel. The jury
18 can't hear you.

19 THE COURT: Thank you.

20 MR. WILLIAMS: I thought it was working. Hello.

21 THE COURT: There you go. Now it's working.

22 MR. WILLIAMS: Is that better? I'll try here,
23 but when I put it on my tie, it rustles a lot.

24 Is this better?

25 THE COURT: It was there for a second and then
26 it went out again.

27 MR. WILLIAMS: Hello.

28 THE COURT: There you go.

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1 UNKNOWN JUROR: We hear you.

2 MR. ROBINSON: Loud and clear.

3 BY MR. WILLIAMS:

4 Q Okay. Let me ask that again. Was the
5 scientific study known as Buz'Zard, which is Exhibit
6 L131, available to and reviewed by the CIR expert review
7 panel at the time they reached their conclusions
8 regarding talc?

9 A Yes, it was.

10 Q Was the scientific study known as the Shukla
11 study, L1138 in this case, from 2009, was that scientific
12 study available to and reviewed by the Cosmetic
13 Ingredient Review?

14 A Yes. That was part of what we looked at.

15 Q Let me turn to another couple of studies.

16 Did the CIR consider studies looking at whether
17 talc causes what's known as adverse cellular effects in
18 human cells?

19 A Yes. There were several studies that looked at
20 human cells in laboratory culture and looked at the
21 effects.

22 Q Was one of those studies a study called Nasreen?

23 A Yes, it was.

24 MR. WILLIAMS: For the record, your Honor,
25 that's Exhibit L887.

26 BY MR. WILLIAMS:

27 Q Dr. Andersen, was one of the scientific studies
28 reviewed by the CIR the study called Lee?

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1 A Yes.

2 Q That's Exhibit L741.

3 Did the CIR find that there were any adverse
4 cellular effects relating to talc?

5 A Not in the cellular studies that were reported.

6 Q Please go ahead.

7 A I think the phrase that the panel adopted was
8 the cellular studies were unremarkable.

9 Q If you could look in your book, the first book,
10 at Exhibit D25.

11 A I'm sorry, E?

12 THE COURT: E or D?

13 MR. WILLIAMS: D as in dog. D25.

14 BY MR. WILLIAMS:

15 Q Which is your report, which attaches the --
16 which attaches the study.

17 Do you have that in front of you?

18 A None of these have a D.

19 Q I know what it will have. Why don't you take a
20 look at Exhibit L384, which is the published version of
21 the study.

22 A Yes.

23 Q We can use that.

24 Let me direct your attention to page 11 of
25 Exhibit L384.

26 A Yes.

27 Q And for the record, we are referring to the
28 final final report of CIR.

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1 Do you see the heading there on page 11,
2 "Cellular Effects"?

3 A Yes, I do.

4 Q And a few moments ago, without the report in
5 front of you, I believe that you used the phrase "No, not
6 remarkable"?

7 A That's correct.

8 Q Was this the portion of the report that you were
9 referring to?

10 A Yes, it was.

11 Q Can you describe for the members of the jury
12 what the CIR concluded with reference to cellular
13 effects?

14 A They didn't really inform the discussion about
15 the safety of talc as used in cosmetics.

16 Q In the report that's in front of you, you see
17 that there are some citations? There's a reference
18 number at the end of the paragraph on cellular effects?

19 A Yes.

20 Q Do you see that it refers to 69 and then 71
21 through 78?

22 A That's correct.

23 Q Could you just flip to the back to the
24 references of the studies that were referenced and verify
25 that the Lee and Nasreen studies were among that range of
26 references?

27 A Yes, they are.

28 Q Did you prepare a slide that summarized the

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1 findings of the Nasreen and Lee studies?

2 A Well, presented a picture of what the results
3 look like, yes.

4 Q Like this? Did you do your slide deck?

5 A Yes.

6 Q Do you have that in front of you?

7 MR. WILLIAMS: All right. Your Honor,
8 permission to publish Slide 9 with the Nasreen and Lee.

9 MR. SMITH: Again, it's not in the four corners
10 of his report. Objection.

11 THE COURT: Overruled.

12 BY MR. WILLIAMS:

13 Q Now, with respect to the Nasreen study, can you
14 describe what -- there's been some testimony earlier,
15 Doctor, regarding what we've been calling apoptosis, but
16 can you describe what apoptosis is.

17 A Well, apoptosis is programmed cell death. For
18 whatever reason, a cell has accumulated some level of
19 insult and, as a result, it dies.

20 Q With respect to the Nasreen study, what was the
21 conclusion of that study with regard to the impact of
22 talc on human cells?

23 A Well, the authors were studying in particular
24 the practical aspects of the medical procedure called
25 "pleurodesis" in which talc is actually injected into the
26 area around the lung for a clinical benefit.

27 And in doing the study, they didn't look at
28 people. They took lung cancer cells in a laboratory in a

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1 culture dish, and they took normal lung cells in culture
2 in a petri dish in a laboratory, and they exposed them to
3 talc. And this captures the exposure to talc resulted in
4 an increase in apoptosis in the cancer cells, but it
5 didn't affect the normal cells.

6 Q With respect to the Lee study, was that a
7 similar type of analysis?

8 A As I read it, the Lee study was actually a
9 letter to the editor, not a full published -- it was
10 published, but it was just a letter to the editor
11 repeating virtually the same finding, that talc affected
12 the lung cancer cells but didn't affect normal cells.

13 Q So the effect that the -- did the exposure of
14 talc to human cancerous lung cells result in programmed
15 cell death for the cancerous cells?

16 A That's what the studies appeared to say, yes.

17 Q Did the exposure of talc to healthy human cells
18 result in cell death for the healthy cells?

19 A No, it didn't.

20 Q The CIR report was finalized in 2013, was it?

21 A That's correct.

22 Q And the -- what you called yesterday the final
23 report was put on the website in 2013?

24 A That's correct.

25 Q But the publication of the final -- what you
26 called the final final report didn't happen until two
27 years later; correct?

28 A That's correct.

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1 Q You were retained by Johnson & Johnson when?

2 A Mid 2016.

3 Q Between the time that you left the CIR in 2013
4 and the time that you prepared your report for this
5 litigation, did you review studies of different types
6 that came out after 2013 when the CIR report was
7 prepared?

8 A Yes, I did.

9 Q Could you describe just generally the types of
10 studies you reviewed.

11 A Well, I think for the most part the data that
12 were newly available were epidemiology studies.

13 Q Did you review epidemiological studies of both
14 the cohort or prospective type and the retrospective
15 case-control type?

16 A There were examples of both newly published. So
17 I looked at them all.

18 Q In your view, did the studies that you reviewed
19 change the total scientific landscape that you had last
20 studied back in 2013 at the time the CIR report came out?

21 A It -- no, I don't think they changed my view of
22 what the epidemiology data allows you to conclude. It
23 looked much more of the same.

24 Q Based on your review of literature and the
25 analysis that you did both in 2011 through 2013 when the
26 CIR report was prepared, and more recently after you left
27 the CIR and reviewed the studies that you just referred
28 to, Doctor, do you consider talc to be safe in the

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1 present practices of use and concentration?

2 A Yes.

3 Q Does the present practice and use -- strike
4 that.

5 Does the present practice of use and
6 concentration include the perineal use of talc?

7 A Yes, it does.

8 MR. WILLIAMS: No further questions, your Honor.

9 THE COURT: All right. Thanks.

10 Mr. Smith.

11 MR. SMITH: Yes, your Honor. Can I have just a
12 second?

13 THE COURT: Sure.

14 MR. SMITH: Thanks.

15 Your Honor. I have a notebook. May I approach?

16 THE COURT: Sure. That's for the witness?

17 MR. SMITH: May I approach?

18 THE COURT: Yes.

19 MR. SMITH: Thank you. And I have some for you,
20 your Honor. Stack them up.

21 THE WITNESS: Wow. I assume the bigger one is
22 Volume 1.

23 MR. SMITH: Yes. We might not go through all of
24 it. I just had it here just in case.

25 May I approach, your Honor?

26 THE COURT: Yes.

27 MR. SMITH: Thanks, your Honor.

28 Can I switch out Volume 2 with you, Judge? We

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1 are going to get this right. The smaller one. Thank
2 you.

3 THE COURT: Thank you.

4 MR. SMITH: Okay. Has everybody got a copy?

5 Good morning, all.

6 ALL: Good morning.

7 CROSS-EXAMINATION

8 BY MR. SMITH:

9 Q Hey, Doctor, how are you doing?

10 A Doing well so far.

11 Q My name is Allen Smith and I represent
12 Ms. Echeverria. And we haven't had the pleasure of
13 talking, have we, before?

14 A I'm sorry?

15 Q We haven't had the pleasure of talking before,
16 have we?

17 A No, we haven't.

18 Q Well, nice to see you. I just have a few
19 questions for you this morning. Okay?

20 A That's fine.

21 Q I want to start where you just left off with
22 defense counsel on the Lee and Nasreen study, and you
23 talked about how those studies showed that talc caused
24 cancer cells to die.

25 Do you recall that?

26 A Yes, I do.

27 Q And you're familiar with radiation, are you not?

28 A Yes, I am.

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1 Q You said you are an expert in that and had very
2 good -- or very familiar with that -- I thought you said
3 you had specialized knowledge regarding radiation in
4 direct. Did I misunderstand that?

5 A No, you didn't. I spent 22 years with radiation
6 protection as part of my responsibilities, so yes.

7 Q And radiation exposure to humans over a chronic
8 or a long period of time can lead to cancer, can it not?

9 A It depends.

10 Q Sure. But it can; it's possible. Correct?

11 A Yes, it's possible.

12 Q And radiation is used to give to patients like
13 my client to kill cancer cells after surgery; correct?

14 A Radiation of different types are used as part of
15 cancer therapy, yes.

16 Q So a similar cancer-causing substance or
17 exposure radiation given chronically over a long period
18 of time can lead to cancer. They can also be given an
19 acute blast exposure to kill cancer cells. Is that not
20 true? It's regularly administered for that.

21 A It depends on the kind of radiation that you're
22 talking about, but there is a circumstance in which, in
23 particular, ionizing radiation can, when given at high
24 doses, targeted exposure, can effectively treat a tumor,
25 yes.

26 Q And I've got other examples of that. HRT.
27 Chemotherapy. We could go down. There's a long list of
28 agents that, when given acutely in high doses, can cause

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1 cancer cells to die and, when given chronically, can lead
2 to adverse medical effects such as cancer; is that right,
3 Doctor?

4 A The generalization that an exposure that is
5 effective in treating a tumor automatically at low doses
6 has an adverse effect is not a generalization that I'm
7 comfortable with. Ionizing radiation in particular
8 happens to fit that pattern. Exposures at low levels to
9 ionizing radiation does present an incremental increase
10 in cancer risk. So at least ionizing radiation, I'm
11 comfortable that that generalization is true.

12 Q All right. We will stick with radiation then.
13 You talked about epidemiological studies since
14 the 2013 CIR report. Do you recall that?

15 A Yes.

16 Q Are you an epidemiologist?

17 A No, I'm not.

18 Q Okay. But you just spoke about the
19 epidemiological data since 2013 when the CIR came out;
20 correct?

21 A That's correct.

22 Q Okay. Are all your opinions contained in your
23 report and all the materials you relied on for your
24 opinions in this case cited in your report?

25 A I believe so.

26 Q And earlier with defense counsel, you talked
27 about your time with the FDA. What years were you there
28 again? I forgot.

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1 A 1971 to 1993.

2 Q So a long period of time?

3 A It seemed like it.

4 Q Sure. And during direct you talked about how
5 you went to all different types of departments, including
6 cosmetics, and were familiar generally with the FDA, how
7 it works, and even talked about labeling at the FDA. Do
8 you recall that?

9 A Yes.

10 Q And so you have -- or you can speak to matters
11 regarding the FDA and its control or lack of control over
12 cosmetics. You have some familiarity with that, do you
13 not?

14 MR. WILLIAMS: Beyond -- excuse me, your Honor.
15 Objection. Beyond the scope.

16 THE COURT: Overruled.

17 BY MR. SMITH:

18 Q You have some familiarity with that, do you not?

19 A I have a familiarity with FDA's regulatory
20 program for cosmetics.

21 Q Okay. And that includes warning language that
22 goes on cosmetics; correct?

23 A Yes, it does.

24 Q Okay. What is the warning language or warning
25 regulation of the FDA regarding cosmetics?

26 MR. WILLIAMS: Your Honor, objection. Beyond
27 the scope.

28 THE COURT: Sustained.

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1 BY MR. SMITH:

2 Q Did you read -- are you familiar with, since you
3 have issued a report and you said all your materials that
4 you relied on in your report, the 1990 -- 2014 FDA
5 response to the citizen's petition on talc?

6 MR. WILLIAMS: Same objection, your Honor.

7 THE COURT: Sustained.

8 BY MR. SMITH:

9 Q At the FDA, in your tenure there, were you
10 familiar with the language that is included in the
11 regulation regarding cosmetics that you spoke about in
12 your deposition and in your report?

13 MR. WILLIAMS: Same objection, your Honor.

14 THE COURT: Sustained.

15 BY MR. SMITH:

16 Q Are you familiar with the FDA regulations
17 regarding warnings, based on your tenure, your knowledge,
18 and experience at the FDA?

19 A In a broad sense, yes, I'm familiar with the FDA
20 concept of labeling in general.

21 Q Could you tell the jury what a voluntary
22 warning -- or paraphrase voluntary warning language
23 regarding the FDA over cosmetics?

24 MR. WILLIAMS: Objection, your Honor. Beyond
25 the scope.

26 THE COURT: Sustained.

27 BY MR. SMITH:

28 Q Are you familiar with the FDA warning language

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1 regarding voluntary warnings on cosmetics?

2 MR. WILLIAMS: Objection. Asked and answered.

3 THE COURT: Sustained.

4 BY MR. SMITH:

5 Q Based on your general knowledge and experience
6 at the FDA, would you agree with me that it is ultimately
7 the companies and manufacturers that are responsible for
8 the safety and labeling of their products?

9 MR. WILLIAMS: Same objection, your Honor.
10 Beyond the scope.

11 MR. SMITH: Goes to his knowledge, general
12 knowledge.

13 THE COURT: No. Overruled given the testimony
14 that he gave about the formation of the CIR and so on.

15 BY MR. SMITH:

16 Q Would you agree with me that it is the
17 ultimate -- it's ultimately the companies and
18 manufacturers that are responsible for the safety and
19 labeling of their products, cosmetic products?

20 A If we could parse that out into the two pieces
21 of your question. The way Congress set up the Food,
22 Drug, and Cosmetic Act, manufacturers are responsible for
23 ensuring the safety of ingredients used in their
24 products. That's where the responsibility is assigned.

25 The labeling is also the responsibility of the
26 manufacturer, but those are implemented via regulations
27 as opposed to Congress having opined.

28 Q And you are familiar with those regulations, as

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1 you stated before; correct?

2 MR. WILLIAMS: Asked and answered, your Honor.

3 THE COURT: Sustained.

4 BY MR. SMITH:

5 Q So, Doctor, based on your knowledge and general
6 experience at the FDA, a manufacturer of a cosmetic
7 cannot say just because the FDA is not mandating a
8 warning, the company is relieved from placing warnings on
9 its cosmetics products; correct?

10 MR. WILLIAMS: It's beyond the scope, your
11 Honor.

12 MR. SMITH: It's based on his general knowledge
13 at the FDA, your Honor.

14 THE COURT: It is beyond the scope. Sustained.
15 BY MR. SMITH:

16 Q Based on your general knowledge at the FDA, are
17 you familiar with adverse incident reports and the like?

18 MR. WILLIAMS: Same objection, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Are you familiar with any voluntary reporting
22 that has to be done by cosmetic companies regarding their
23 products?

24 MR. WILLIAMS: Same objection, your Honor.

25 THE COURT: Scope. Sustained.

26 BY MR. SMITH:

27 Q While at the FDA, since you said that you dealt
28 in different areas including cosmetics, would you also --

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1 would the FDA also look to what others in the industry
2 were doing regarding labeling of their cosmetics?

3 MR. WILLIAMS: Same objection, your Honor.

4 THE COURT: Sustained.

5 MR. WILLIAMS: Not been any evidence given.

6 BY MR. SMITH:

7 Q You said that you were a labeling expert and you
8 had expertise at this at the FDA; correct?

9 MR. WILLIAMS: Your Honor, may we be heard?

10 THE COURT: Sustained. We don't need to be
11 heard further on this.

12 MR. WILLIAMS: Thank you, your Honor.

13 THE COURT: Mr. Smith.

14 BY MR. SMITH:

15 Q Are cosmetics preapproved by the FDA before they
16 go on the market like drugs?

17 MR. WILLIAMS: Same objection.

18 THE COURT: Overruled.

19 THE WITNESS: As you phrased the question, the
20 answer is it depends.

21 BY MR. SMITH:

22 Q So baby powder has to be preapproved before it
23 goes on the market by the FDA?

24 A No.

25 MR. WILLIAMS: That's argumentative, your Honor.
26 Misstates the question.

27 THE COURT: Sustained.

28 ///

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1 BY MR. SMITH:

2 Q Does baby powder have to be preapproved by the
3 FDA before it went on the market?

4 A No, it does not, unless it contains a color
5 additive. FDA must approve color additives before they
6 go on the market.

7 Q Are you aware if Johnson's baby powder contains
8 a color additive?

9 A I don't know. I just was telling you what the
10 rules are.

11 Q If baby powder, I'll represent to you, is
12 99 percent talc and 1 percent fragrance, would that
13 contain a color additive?

14 A No.

15 Q Would you agree that the cosmetic industry for
16 the most part is self-regulatory?

17 MR. WILLIAMS: Same objection, your Honor.
18 Beyond the scope.

19 THE COURT: Overruled.

20 THE WITNESS: Not in any regard.

21 BY MR. SMITH:

22 Q You don't agree with that statement?

23 A No, I don't.

24 MR. SMITH: Do you have his deposition?

25 BY MR. SMITH:

26 Q Give me just a minute, Doctor. I'm going to
27 pull out my red notebooks.

28 MR. SMITH: May I approach -- I'll give the

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1 defendants --

2 MR. WILLIAMS: Thank you.

3 MR. SMITH: Oh, you need a copy.

4 THE COURT: That's okay.

5 MR. SMITH: Permission to read page -- let me
6 get to it, your Honor. Permission to read line 11
7 through 19.

8 THE COURT: Of what page?

9 MR. SMITH: Oh, I'm sorry. 152.

10 THE COURT: Thank you.

11 MR. SMITH: May I proceed?

12 MR. WILLIAMS: May I have a moment?

13 I'm sorry. What were the line numbers, your
14 Honor?

15 THE COURT: 152, 11 through 19.

16 MR. WILLIAMS: No objection.

17 BY MR. SMITH:

18 Q Question to you -- do you remember being deposed
19 under oath?

20 A Yes.

21 Q A question was asked to you:

22 "Is the cosmetic industry
23 self-regulated?"

24 Your answer was:

25 "That is their intent. It is
26 my" --

27 MR. WILLIAMS: Sorry. I thought that was a
28 stop. I apologize, your Honor. I thought counsel had

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1 stopped.

2 MR. SMITH: May I continue?

3 THE COURT: Yes.

4 BY MR. SMITH:

5 Q Okay.

6 "It is in my own global view as a
7 regulatory scientist with 40 years'
8 experience, it's not entirely true. The
9 efforts clearly that occur in Europe are
10 not self-regulatory. Dealing with
11 Prop 65 in California is not
12 self-regulatory. But the CIR effort is
13 certainly what the trade association
14 touts as their self-regulatory
15 contribution."

16 Did I read that correctly?

17 MR. WILLIAMS: Actually, it says "being their
18 self-regulatory contribution," your Honor.

19 BY MR. SMITH:

20 Q Is that correct?

21 A I think I said that very well.

22 Q Did you? I thought you said to me under oath in
23 no way is that correct when I asked if it was
24 self-regulatory. I thought that was your response. I
25 can have it read back to you if you would like.

26 MR. WILLIAMS: There's no question pending, your
27 Honor.

28 ///

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1 BY MR. SMITH:

2 Q Do you remember saying that?

3 A I remember answering your question by saying no.

4 Q You don't recall saying any more than that?

5 A I'm lost.

6 Q Okay. We'll move on.

7 The FDA does not require, based on your
8 knowledge and experience, cosmetic companies to share
9 safety information with the FDA; is that correct?

10 A Does not require? No. FDA, according to the
11 Food, Drug, and Cosmetic Act, except for color additives,
12 does not require safety data to be submitted.

13 Q And the FDA cannot require a recall of a
14 cosmetic; is that correct?

15 MR. WILLIAMS: Your Honor, that's beyond the
16 scope.

17 THE COURT: Sustained.

18 BY MR. SMITH:

19 Q Do you have general knowledge about the FDA and
20 what they can and cannot do regarding cosmetics based on
21 what your testimony was on direct?

22 MR. WILLIAMS: Asked and answered, your Honor.

23 THE COURT: Overruled.

24 BY MR. SMITH:

25 Q Doctor?

26 A Yes, I think I do.

27 Q And do you know whether or not the FDA, based on
28 your knowledge and experience at the FDA, can require a

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1 recall of a cosmetic product?

2 MR. WILLIAMS: That's the same question. Beyond
3 the scope.

4 THE COURT: Sustained.

5 BY MR. SMITH:

6 Q Okay. Let's talk about Dr. Andersen for a
7 second, because I haven't had the pleasure of meeting
8 you.

9 Have you ever seen or treated Mrs. Echeverria?

10 A No, I have not.

11 Q Besides the CIR that you've talked about with
12 defense counsel, have you ever lectured, publicate -- had
13 any publications or studies on talc and ovarian cancer?

14 A Yes.

15 Q On talc and ovarian cancer both together besides
16 the CIR?

17 A Oh, I'm sorry. Did you put that caveat of
18 besides the CIR?

19 Q Yes, sir.

20 A I'm sorry.

21 No, I have not.

22 Q And while you were at the FDA, did you have any
23 epidemiological data that you reviewed that dealt with
24 talc?

25 A No, I didn't.

26 Q You're not an epidemiologist?

27 A No, I'm not.

28 Q You're not a toxicologist?

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1 A Not by training.

2 Q What does that mean? What does "not by
3 training" mean?

4 A My responsibilities as a regulatory scientist,
5 as a member of FDA senior executive service, was to be
6 knowledgeable about all of the kinds of data:
7 laboratory, animal, included toxicology, clinical
8 studies. And while I'm not an epidemiologist, frankly, I
9 was responsible for factoring in what's the impact of the
10 findings from epidemiology studies. That's what a senior
11 FDA official does.

12 Q And as a senior FDA official, you would be
13 familiar with the regulations regarding warnings on
14 cosmetics; correct?

15 A I'm aware of the FDA requirements for warnings
16 on products in general.

17 Q What are they?

18 MR. WILLIAMS: Your Honor, objection. That's
19 beyond the scope.

20 THE COURT: Sustained.

21 BY MR. SMITH:

22 Q All right. You talked about toxicology not by
23 trade. The jury has heard from one of my experts,
24 Dr. Laura Plunkett. It's the first witness I brought.
25 She's a toxicologist. She testified about what she had
26 to do to be a certified toxicologist.

27 MR. WILLIAMS: Objection to the preamble, your
28 Honor. It's not a question.

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1 THE COURT: Sustained.

2 MR. WILLIAMS: It's argumentative.

3 BY MR. SMITH:

4 Q Let me ask you this: Have you gone through the
5 certification as a toxicologist under the American Board
6 of Toxicology?

7 A No. I have not, no.

8 Q Are you a paid expert for the defendants in this
9 case?

10 A Yes, I am.

11 Q And what is your hourly rate?

12 A \$695 an hour is what the firm charges for my
13 services.

14 Q And that firm is EAS Consulting Group; correct?

15 A Yes.

16 Q And EA -- excuse me -- that's a
17 tongue-twister -- EAS Consulting Group has a website;
18 correct? You're familiar with that.

19 A Familiar would be extending it. I know that it
20 exists.

21 Q Sure.

22 MR. SMITH: And, Jeff, I'd like to go to P940.
23 It's the website of EAS Consulting.

24 May I publish it, your Honor?

25 THE COURT: Any objection?

26 MR. WILLIAMS: May I have a moment, your Honor?

27 No objection.

28 THE COURT: Go ahead, Counsel.

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1 BY MR. SMITH:

2 Q All right. This is EA -- I can't say it -- EAS
3 Consulting Group. Easy for me to say.

4 And this is where you're a consultant; right?

5 A I'm an independent consultant associated with
6 the EAS Consulting Group.

7 Q Well, the defendants write the checks "EAS
8 Consulting"; right?

9 A I'm sorry?

10 Q Do the defendants that hired you in this case,
11 do they write them to you personally or EAS Consulting
12 Group?

13 A To EAS Consulting.

14 Q Okay. "Specializing in FDA regulatory matters."
15 Do you see that?

16 A Yes.

17 Q Okay.

18 And, Jeff, if we can go down into the gray right
19 here.

20 Can y'all see that? Everybody can see that?

21 "EAS Consulting Group specializes
22 in FDA regulatory matters. Our prime
23 focus is to assist domestic and foreign
24 pharmaceutical, medical device, tobacco,
25 food, dietary supplement, and cosmetic
26 firms comply with applicable laws and
27 regulations."

28 Is that what you understand your consulting

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1 group to do?

2 A Yes.

3 Q Okay. And do you know John Bailey, Dr. Bailey?

4 A Yes, I do know Dr. Bailey.

5 Q Do you know him personally and professionally or
6 just professionally?

7 A It's hard not to be both.

8 Q Okay.

9 I'd like to go to another part of the website,
10 your Honor. It's P943.

11 And there he is -- I've printed this off the EAS
12 site -- John Bailey, Ph.D. And he is an independent
13 adviser, colors and cosmetics.

14 He was formerly at the FDA, was he not?

15 MR. WILLIAMS: Objection. Relevance. Beyond
16 the scope.

17 MR. SMITH: He said he knew him personally and
18 professionally, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Do you know whether or not Dr. Bailey worked at
22 the FDA?

23 MR. WILLIAMS: Relevance, your Honor.

24 THE COURT: Sustained.

25 BY MR. SMITH:

26 Q Regardless, John Bailey works at EAS Consulting;
27 correct?

28 A That's my understanding.

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1 Q Was Mr. Bailey at the FDA while you were there?

2 MR. WILLIAMS: Relevance, your Honor.

3 THE COURT: Let me see counsel at sidebar.

4 (The following proceedings were had
5 at the sidebar out of the hearing of the
6 jury:)

7 THE COURT: What's your offer of proof as to the
8 relevance?

9 MR. SMITH: He talks about the FDA later on.
10 I'm going to set up that Mr. Bailey was the one that
11 responded to the citizen's petition, and he also went to
12 work for the PCPC when he was working for CIR. That's
13 all I'm setting up. He used to be a former employee of
14 the FDA. It says it on his bio.

15 MR. WILLIAMS: Your Honor, clearly beyond the
16 scope.

17 Secondly, Dr. Bailey did not write the response.
18 The response came from someone else at FDA to the citizen
19 petition.

20 Third, this whole line of questioning, almost
21 90 percent of what counsel has done is on the area that
22 is not relevant and beyond the scope of the direct. And
23 he's making me have to object over and over and over
24 again, knowing -- knowing that the Court has ruled that
25 this is not appropriate.

26 So it is a total side issue. He shouldn't be
27 permitted to just talk about John Bailey and try to
28 testify to facts that are outside the record through this

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1 witness.

2 MR. SMITH: Your Honor, the witness is from the
3 FDA where this guy used to work. I mean, if I'm going to
4 tie it up later -- and this guy also went to work with
5 PCPC. He is the one that went to meetings with Johnson &
6 Johnson and meetings on the citizen's petition with the
7 federal government. Now, I'll -- how am I -- I
8 believe -- I think John Bailey worked with him at FDA.

9 THE COURT: Why is that relevant -- why is his
10 knowledge of John Bailey relevant to anything as an
11 expert witness in this case on the stand?

12 MR. SMITH: I think it goes to the relevance of
13 the citizen's petition, to which he has intimate
14 knowledge of the FDA's ruling and of the PCPC.

15 THE COURT: The objection is sustained.

16 (The following proceedings were
17 held in open court in the presence of
18 the jury:)

19 BY MR. SMITH:

20 Q Okay. We were at the EAS Consulting Group
21 website. And I finally said it right.

22 I want to go to a different part of that
23 website. It's P942. It's partnerships and affiliates of
24 the consulting group of which you're a consultant.

25 MR. SMITH: Permission to publish 942, your
26 Honor.

27 THE COURT: Any objection?

28 MR. WILLIAMS: May I just have a moment, your

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1 Honor?

2 No objection.

3 BY MR. SMITH:

4 Q This is partnerships and affiliates of EAS
5 Consulting Group.

6 And if we could go to the second page, Jeff.
7 You see this -- can you blow that up.

8 Consumer Healthcare Products Association, CHPA.
9 It's a -- Consumer Healthcare Products Association,
10 that's affiliated with the EAS Consulting Group for which
11 you're a consultant.

12 Do you see that?

13 MR. WILLIAMS: Lacks foundation, your Honor.

14 THE COURT: The question is does he see it.
15 Overruled.

16 BY MR. SMITH:

17 Q Do you see that, Doctor?

18 A Yes. It's on the screen.

19 Q Did you know that Johnson & Johnson employees
20 are on the board of director of the CHPA?

21 A No, I --

22 MR. WILLIAMS: Assumes facts. "Did you know"?

23 THE COURT: Sustained.

24 BY MR. SMITH:

25 Q Well, let's go to it. It's P938.

26 MR. SMITH: Your Honor, I'd like to publish the
27 CHPA board of directors and other directors.

28 MR. WILLIAMS: Your Honor, relevance.

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1 MR. SMITH: Goes to --

2 MR. WILLIAMS: And lacks foundation.

3 MR. SMITH: Your Honor, they're -- Johnson &
4 Johnson is affiliated with this company he's a consultant
5 with. I think it's highly relevant.

6 It's on page 4 of 76 and 6 of 76 in that
7 document.

8 MR. WILLIAMS: Same objection, your Honor.

9 THE COURT: Overruled.

10 MR. SMITH: Thank you.

11 Jeff, can we go to P938.

12 BY MR. SMITH:

13 Q Here's the CHPA for which the consulting firm
14 that you work for, EAS Consulting Group, which you are a
15 consultant for, is affiliated with the CHPA that we just
16 saw.

17 Do you remember that?

18 A Yes.

19 Q And here's the board of directors for 2016 and
20 '17.

21 If we can go to page 4 of whatever, Jeff. I
22 can't remember now. 4 of something.

23 And it says "Board of Directors."

24 There's Kathleen M. Widmer, J&J Consumer Inc.,
25 McNeil Consumer Healthcare division.

26 Did you realize that J&J Consumer Inc. is a
27 defendant in this case?

28 A Yes, I guess I did.

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1 Q Do you know Kathleen Widmer?

2 A No, I don't.

3 MR. SMITH: Can we go to page 6 of whatever
4 page, Jeff.

5 BY MR. SMITH:

6 Q And it has Educational Foundation Board of
7 Directors.

8 Joy-Lee Pasqualoni -- if I can't say EAS; I'm
9 probably not going to be able to say that -- Johnson &
10 Johnson Consumer Inc. Is J&J Consumer Inc. a defendant
11 in this case?

12 A Yes. What I don't know is what the CHPA
13 Educational Foundation is.

14 Q But, regardless, the consulting group for which
15 you're a consultant is affiliated with the CHPA where
16 Johnson & Johnson sits on whatever board of directors
17 that I just showed you for 2016 and '17; correct?

18 A The CHPA Educational Foundation, yes.

19 Q Okay.

20 Next, I would like to go to your CV. You
21 issued -- you have a CV, which is just your resume in
22 this case; is that correct?

23 A Yes.

24 Q And if we could go to that.

25 MR. SMITH: It's D5, Jeff.

26 Permission to publish his CV, your Honor.

27 THE COURT: Any objection?

28 MR. WILLIAMS: No objection.

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1 MR. SMITH: I think it's right in here, Jeff. I
2 think it's '93 to 2013, I think.

3 BY MR. SMITH:

4 Q '93 to 2013. So that's 20 years, if my math is
5 right.

6 A That's correct.

7 Q "Director of Cosmetic Ingredient Review." And
8 that's the CIR that we've been talking about; right?

9 A Yes.

10 Q "Recruited to head the Cosmetic Ingredient
11 Review, Food & Drug Administration. Established in 1976,
12 the then Cosmetic Toiletry and Fragrance Association" --
13 that's known as the CTFA; right?

14 A Yes.

15 Q Now the Personal Care Products Council -- which
16 is now known as the PCPC or can be called the PCPC;
17 correct?

18 A Yes.

19 Q Okay.

20 "CIR is a unique endeavor by the
21 industry to have the safety of
22 ingredients used in cosmetics thoroughly
23 reviewed and assessed in an open,
24 unbiased, and expert manner."

25 And then it talks about what the director does.
26 And that was you; correct?

27 A Yes.

28 Q I want to talk about the CIR for a minute.

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1 Thank you, Jeff.

2 In your deposition -- and I wrote this down; and
3 correct me if I'm wrong -- you said the interaction
4 between the CIR and the industry group, the PCPC, you
5 would only go kicking and screaming regarding the
6 interaction between the two and that basically the CIR
7 was completely independent from the PCPC and industry and
8 you took pride in that.

9 Do you recall saying something to that effect?

10 MR. WILLIAMS: Objection to the extent it
11 misstates the testimony.

12 MR. SMITH: I can get the testimony if we need
13 it. I just thought we could short-circuit --

14 THE COURT: I don't have the testimony, so I
15 can't rule on the objection.

16 MR. WILLIAMS: I'll withdraw it, your Honor.

17 BY MR. SMITH:

18 Q Do you recall saying something to that effect?
19 And I can pull --

20 A That sounds like the way I would have responded
21 to that kind of question.

22 Q And the CIR was created in 1976; is that
23 correct?

24 A Yes, it was.

25 Q And, like you said in your CV, so that cosmetic
26 companies could substantiate their safety -- right? -- in
27 part?

28 A Well, no.

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1 Q Okay. So the CIR does not rule on the safety of
2 cosmetics?

3 A It does. It is the word "substantiate" that I'm
4 having a problem with.

5 Q All right. Well, maybe I'm not saying --

6 A CIR reviews and assesses the safety of
7 ingredients used in cosmetics.

8 Q Okay. So the CIR was created in 1976; right?

9 A Yes.

10 Q And it reviews the safety of cosmetics?

11 A Yes.

12 Q Okay. Now, so that the jury gets a kind of a --
13 what we're talking about here, the PCPC -- so if I say
14 "PCPC," it was formerly known as the CTFA. So if I say
15 "PCPC," can we have that kind of definition that they
16 were also known as the CTFA prior?

17 A It would help immensely.

18 Q Okay. Thanks. I don't want to say all those
19 acronyms.

20 But the PCPC totally funds the CIR; correct?

21 A Yes, it does.

22 Q And Johnson & Johnson and their supplier of
23 talc, Imerys, formed a Talc Interested Party Task Force
24 for talc issues at the PCPC. We talked about it in your
25 deposition. Do you not recall that?

26 A No, I don't. I think I may have been aware that
27 such a group existed, but that would have been it.

28 Q Let me go to my red binder here.

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1 MR. SMITH: Your Honor, permission to read his
2 sworn deposition testimony, page 195 to, I think, line
3 16 -- 1 through 16.

4 MR. WILLIAMS: May I have the lines, your Honor?

5 THE COURT: 1 through 16, page 195.

6 MR. WILLIAMS: On 195?

7 Not proper impeachment, your Honor. He says he
8 doesn't know what it was.

9 THE COURT: Overruled. Go ahead.

10 BY MR. SMITH:

11 Q Okay.

12 "Question: Do you know what the
13 Talc Interested Party Talc Force is?"

14 And your answer was:

15 "Answer: Not really."

16 And the question was:

17 "Question: You never heard of
18 that?

19 And your answer:

20 "Answer: Oh, I've heard of it. I
21 just -- you asked do I know what it is.

22 "Question: You've heard of it. Do
23 you know what it was about? Do you know
24 anything about it?

25 There was an objection to form.

26 And you answered:

27 "Answer: I guess in a broad sense
28 I'm aware that the industry trade

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1 association would gather particular
2 members who had an ax to grind on a
3 particular issue and bring them together
4 to talk about that issue. I think that
5 was the genesis of the interested party
6 piece of the description. What they
7 really did, I don't have a clue."

8 Do you recall saying that?

9 A It sounds exactly like how I would have said it.

10 Q So the Talc Interested Party Task Force that the
11 two defendants formed under the PCPC had an ax to grind
12 on talc-related issues?

13 MR. WILLIAMS: Assumes facts and lacks
14 foundation.

15 THE COURT: Sustained.

16 BY MR. SMITH:

17 Q Those were your words, were they not?

18 MR. WILLIAMS: Same objection, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Did I just read your testimony correctly?

22 A Yes, you did.

23 Q Thank you.

24 THE COURT: Counsel, may I ask you to do the
25 following for the benefit of the court reporter: When
26 you read deposition testimony, just slow down a little
27 bit.

28 MR. SMITH: I've been accused of that. I get a

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1 little fired up, your Honor. I will slow down.

2 THE COURT: Question, answer; question, answer.

3 MR. SMITH: Sure. I apologize.

4 BY MR. SMITH:

5 Q Sir, I want to -- let's do this.

6 Doctor, I'm going to -- these jurors can't see
7 it. I'm going to kind of tilt it back and forth, if
8 that's okay.

9 A Works for me.

10 Q All right. So we got the CTFA. I did this in
11 opening statement for the jury, but I want to remind
12 them.

13 So we have the CTFA -- can you see that?

14 A Yes.

15 Q The CTFA. And it's now called the PCPC. And
16 that's the trade organization for which these defendants
17 are members of; right?

18 A Trade association.

19 Q Trade association; correct?

20 A That's correct.

21 Q And they pay dues, these defendants as well as
22 other people that are members -- other cosmetic companies
23 that are members of the PCPC, they pay dues, do they not?

24 A That's my understanding.

25 Q And it's your understanding of the PCPC that
26 they pay annual dues based on the size of the company or
27 their income? It's a proportional payment system?

28 A I'm not privy to the details, but I think what I

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1 had heard is that it's -- neither of the two things you
2 said were specific. It related to sales.

3 Q Okay. To sales?

4 A Yeah.

5 Q Do you know if Johnson & Johnson does a lot of
6 sales?

7 A I haven't got a clue.

8 Q Okay.

9 A I apologize -- that is my fallback position of
10 sometimes answering questions.

11 No, I don't know.

12 Q Is Johnson & Johnson, in your opinion, a
13 mom-and-pop organization?

14 A Boy, I'm not sure I know how to answer that
15 question. It was at its inception.

16 Q Sir, I'm --

17 A I'm just --

18 Q This is 2017. I'm not talking about 1893.

19 A Yeah. I think it's fair to say that J&J is a
20 large collection of healthcare and consumer products
21 companies.

22 Q And under the CTFA, these defendants, with their
23 supplier, Imerys, formed the Talc Interested Party Task
24 Force that we just went over in your deposition
25 testimony.

26 Do you recall that?

27 MR. WILLIAMS: Your Honor, that lacks foundation
28 with this witness.

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1 THE COURT: Sustained.

2 BY MR. SMITH:

3 Q You were aware of a Talc Interested Party Task
4 Force, as testified to in your deposition that we just
5 read; correct?

6 A I knew it existed.

7 Q Okay. And so money is paid here by those
8 defendants, just like we talked about?

9 MR. WILLIAMS: Excuse me, your Honor. Objection
10 to the form of the question. Counsel is drawing and
11 essentially testifying without eliciting testimony from
12 the witness. It's improper. It assumes facts not in
13 evidence.

14 MR. SMITH: It is cross-examination, your Honor.
15 I'm just trying to set up a question.

16 THE COURT: I appreciate that.
17 Go ahead, Counsel.

18 MR. SMITH: Thank you.

19 THE COURT: Keeping in mind what the witness
20 said about what he does and doesn't know.

21 MR. SMITH: Yes, your Honor. Thank you.

22 BY MR. SMITH:

23 Q So CTFA, PCPC, Talc Interested Party Task Force,
24 and then the CIR was created. And it's funded solely by
25 the PCPC; right?

26 A If you could back up just a second. On your
27 chart, you put something in parentheses.

28 Q Defendants and Imerys --

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1 A And I have no idea what that --

2 Q I'm sorry. That's just meant to be defendants.

3 A Ahh, that's delta.

4 Q Yes. I'm sorry.

5 A Ahh, okay.

6 Q Okay.

7 MR. WILLIAMS: Pardon me.

8 Thank you, your Honor.

9 BY MR. SMITH:

10 Q CIR funds, solely funds -- is solely funded by
11 the PCPC; right? Is that correct?

12 A Your --

13 Q I'm sorry?

14 A Your podium is blocking me from seeing the --

15 Q Okay. Let me ask you this.

16 THE COURT: Counsel --

17 BY MR. SMITH:

18 Q Does the CIR --

19 A Okay.

20 Q Is the CIR funded solely by the PCPC?

21 A That's my understanding, yes.

22 Q And then the CIR reviews cosmetics from
23 companies from the CTFA, or PCPC, for safety; correct?

24 A Yes.

25 Q Okay. Forgive my writing. Okay.

26 MR. WILLIAMS: Could I just ask -- at least ask
27 counsel to say what he's writing so I don't have to keep
28 walking? If he can say the words, that would be really

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1 helpful.

2 MR. SMITH: Sure.

3 I state -- I have an arrow pointing to PCPC and
4 state that the CIR reviews cosmetics for safety of the
5 PCPC. That's what I said.

6 MR. WILLIAMS: Thank you.

7 BY MR. SMITH:

8 Q Is all that right?

9 A It's "Reviews" --

10 Q "Reviews cosmetics for safety from the PCPC."

11 A I don't understand the "from the PCPC." We
12 review ingredients for safety. I'm not sure what the
13 "from the PCPC" means.

14 Q Okay. Let me clarify.

15 Reviews cosmetics for safety for companies that
16 are members of the PCPC.

17 A Ahh. Okay. The ingredients that are reviewed
18 for safety, I guess, must be manufactured by somebody,
19 and many of them are members of the PCPC.

20 But as the process works, there really isn't
21 that link. The PCPC funds it. The Cosmetic Ingredient
22 Review expert panel is -- has the sole discretion in
23 picking which ingredients are going to be reviewed.

24 So it's that "for the PCPC" that I'm having
25 trouble with.

26 Q I'm trying to --

27 A If it is monetary, if that's what you are
28 referring to, yes, all the money comes from PCPC.

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1 Q Okay. And they review cosmetics from companies
2 that are in the PCPC for safety; is that correct?

3 If I'm a member of the PCPC and I'm a cosmetic
4 company, does the CIR review my cosmetics for safety?

5 A It reviews the ingredients used in your
6 cosmetics for safety.

7 Q Thank you.

8 Okay. In your CV, you stated that you worked at
9 the -- as director at CIR -- was it 20 years, '93 to
10 2013?

11 A That's correct.

12 Q How much were you paid a year?

13 A I don't keep that kind of information in my
14 head.

15 Q How about this. In your deposition, you said
16 approximately \$300,000 a year. Does that sound about
17 right?

18 A Yeah, that's a good ballpark to hear.

19 Q So for about 20 years the PCPC members paid your
20 salary?

21 A That's correct.

22 Q And the PCPC members, one of them that pays dues
23 according to sales is the defendants --

24 A Okay.

25 Q -- correct?

26 A That cascade of logic is correct.

27 Q And I'm not a mathematician, but 20 years times
28 \$300,000 equals -- is it 6 million?

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1 A Boy, I wish that I had made 300K a year for
2 20 years.

3 Q Hold on. Hold on. I just asked you what you
4 made as director, and you said -- you said in your
5 deposition it was \$300,000 a year.

6 A That's correct.

7 Q Is 300,000 times 20 years \$6 million? is my
8 question.

9 A Well, that's certainly true.

10 Q Paid for by members of the PCPC and their dues
11 to the PCPC; is that correct?

12 A I'm just trying -- I don't think there was any
13 other source of funding for the PCPC. So the answer is
14 yes.

15 Q And we talked about the kicking and screaming in
16 your deposition testimony, you used that word about the
17 fierce independence between industry, the PCPC, and the
18 CIR. Do you recall that?

19 A Yes.

20 Q Okay.

21 A It was part of our way of doing business.

22 Q Okay. Well, let's go to -- let me ask you this
23 about that independence. The PCPC office in Washington,
24 D.C., is it in the same -- on the same street -- or
25 excuse me, in the same city, on the same street, in the
26 same building, on the same floor, and on the same suite
27 as the PCPC?

28 A Are you talking about when I was there or

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1 currently?

2 Q I'm talking about currently. The CIR and the
3 PCPC, are they in the same city, the same --

4 A I can short-circuit you. You don't have to go
5 through it again.

6 I've never been there, but my understanding is
7 they share the same offices.

8 Q Same suite?

9 A That's what I said.

10 Q Okay. And you talked to defense counsel about
11 the track record of the CIR for the past -- since 1976 --
12 41 years? '76, is that -- 2017, is that 41 years?

13 A It's approaching 41 years, yes.

14 Q 41 years.

15 A Celebrated the 40th anniversary last fall.

16 Q Congratulations. 41 years, PCPC reviewing
17 cosmetics.

18 You said approximately 5,000 have been reviewed
19 in that time period; correct?

20 A Yes.

21 Q And a whopping 13 were unsafe; right?

22 MR. WILLIAMS: That's argumentative as phrased,
23 your Honor.

24 BY MR. SMITH:

25 Q Were 13 unsafe during that time period?

26 A That's the current status, yes.

27 Q That's 1/5 of 1 percent of the cosmetics that
28 you reviewed in that 41-year period; correct?

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1 A I'll trust your math.

2 Q Okay. I saw a quote from you in -- is it 2012
3 or '13? I can't remember.

4 MR. WILLIAMS: Objection. Assumes facts, your
5 Honor. Improper form.

6 MR. SMITH: I'm just trying to set up the
7 question.

8 THE COURT: Let's just ask the question.

9 BY MR. SMITH:

10 Q Have you said that the CIR annual budget is "not
11 a matter of public record"?

12 A I believe I have said that, yes.

13 Q Why is it not a matter of public record?

14 A Because it's not a matter of public record.

15 Q Why not?

16 A I -- I'm not sure I know how to answer that.

17 Q Can you tell me what the annual budget was the
18 last year you left for the CIR?

19 A No.

20 Q Why not?

21 A I just don't remember.

22 Q Well, you were director for 20 years, sir. You
23 can't tell me what the budget was when you were there in
24 your last year? What was that? How long ago was that?
25 That's four years ago. You can't give me an
26 approximation?

27 A No, I can't.

28 Q So I can't ask you a question so this jury knows

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1 how much -- the totality of the money that the cosmetic
2 companies contribute to the PCPC and how that money is
3 divvied out and where?

4 MR. WILLIAMS: Argumentative.

5 THE COURT: Overruled.

6 You can answer the question, sir.

7 BY MR. SMITH:

8 Q It is not a matter of public record; correct?

9 A It relies on me remembering what that budget
10 was, and I just -- it's not a piece of information that
11 really sticks in my mind. The -- and the explanation for
12 that is that the funding was always adequate to do what
13 the CIR wanted to do. It wasn't a situation where we had
14 to even justify what the budget was going to be for the
15 coming year.

16 The plan for CIR was to do the scientific
17 review, to have the four meetings a year, to prepare all
18 the review materials for the panel to look at, and the
19 industry funded that. So the issue of what was the
20 funding level just wasn't an issue I ever had to really
21 deal with. Whatever we needed, they provided.

22 Q I have --

23 MR. WILLIAMS: Your Honor, if I may, could I
24 just ask counsel to say what he just was writing on the
25 board when Dr. Andersen was speaking?

26 MR. SMITH: I just put his name at the top of
27 that.

28 MR. WILLIAMS: Thank you.

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1 THE WITNESS: Spell it correctly, please.

2 MR. SMITH: Oh. How about that. Is that okay?

3 THE WITNESS: That's better. Thank you.

4 BY MR. SMITH:

5 Q I have no doubt that you were provided what you
6 needed. My question was, do you know what that budget
7 was? Can you tell the jury what the budget was the last
8 year you were there?

9 A I had already answered that. No, I can't. It
10 just -- that budget figure never had a place in my memory
11 chips.

12 Q When you retired after 20 years from the CIR,
13 did you get a retirement package?

14 A I'm not sure what you mean by retirement
15 package. There was a retirement plan that I worked
16 under, and it provided a benefit, yearly benefit on
17 retirement.

18 Q What is that?

19 A Well, I think it's -- I'm not even sure --
20 93,000 a year.

21 Q For how long?

22 A Until I die.

23 Q So while you are here giving testimony about the
24 safety of the defendants' products in front of this jury,
25 you are paid six million dollars partly by funds from
26 Johnson & Johnson, and you are getting a retirement
27 package of \$93,000 a year as we currently sit here based
28 off of that work with the PCPC.

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1 MR. WILLIAMS: Argumentative as phrased.

2 THE COURT: Overruled.

3 THE WITNESS: Yes, I get that retirement
4 benefit.

5 BY MR. SMITH:

6 Q Let's talk about the CIR on talc. Okay? Is
7 that okay? Sir?

8 A Yes.

9 Q Okay. The CIR did not conduct any independent
10 studies itself when it assessed the study of talc;
11 correct?

12 A No, it didn't.

13 Q Okay. So it gathered information that was in
14 the public domain, brought it together with the process
15 you talked about with defense counsel, and arrived at the
16 opinion that you gave, the CIR gave; correct?

17 A That's correct.

18 Q Okay. And the CIR published its final report,
19 review of talc that you have gone over with defense
20 counsel, in 2013; is that right?

21 A That's correct.

22 Q And so that's four years ago.

23 When did the literature search in years stop
24 that went into the 2013 CIR report? Do you remember?

25 A I believe it was 2012.

26 Q 2012. Okay. So five years ago is when the
27 literature stopped that went into the assessment of the
28 CIR on talc; right?

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1 A Yes.

2 Q Okay. Industry provided input to the CIR on
3 talc and wrote letters to you both -- well, wrote letters
4 to you with this input; correct?

5 A Yes.

6 Q And I would like to go over some of those
7 letters that you went over in your deposition that are to
8 you.

9 And I would like to first post EE572.

10 MR. WILLIAMS: Objection, your Honor. It
11 appears to be a draft, if I'm looking at the right one.

12 THE COURT: Yeah. I don't have EE572 in my
13 book, I don't think, Mr. Smith. I have a series of P
14 exhibits, no E exhibits. And in another book I have D
15 exhibits, P exhibits, but no E exhibits.

16 MR. SMITH: Do you have it, Doctor?

17 THE COURT: I don't have it, Counsel.

18 THE WITNESS: I don't know where I would look.

19 MR. SMITH: Look in your notebook.

20 Can I approach, your Honor?

21 THE COURT: Yes.

22 MR. SMITH: I'm sorry. Let's get on the same
23 page. It's here, your Honor. Just look at 572. See,
24 here are the tabs, right here.

25 THE WITNESS: I see it. You can't see the
26 letters.

27 MR. SMITH: Yeah. The letters are blocked,
28 that's the problem.

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1 Do you see 572, your Honor?

2 THE COURT: Got it.

3 MR. SMITH: Okay. Thank you.

4 THE COURT: This is a --

5 MR. SMITH: Can I ask the witness?

6 THE COURT: Yeah.

7 BY MR. SMITH:

8 Q Doctor, you have 572 in front of you?

9 A I do.

10 Q And you discussed this in your deposition, did
11 you not? Do you remember being questioned about it?

12 MR. WILLIAMS: Objection. May we be heard?

13 THE COURT: Yes.

14 If you all want to stand up and stretch for a
15 second, please go ahead.

16 (The following proceedings were had
17 at the sidebar out of the hearing of the
18 jury:)

19 MR. WILLIAMS: Your Honor, my objection is,
20 number one, counsel doesn't have a good faith basis to
21 put this in front of the witness. It's a draft letter
22 that the witness testified to in deposition that he had
23 no idea, had never seen before. So for him to pull this,
24 it is an internal Imerys document, a draft, with the
25 Imerys Bates number on it.

26 So, again, it is a question designed to make us
27 have to object, knowing that we will object in front of
28 the jury when counsel has no bases for asking this

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1 witness about it.

2 The purpose of the deposition is to ask whether
3 a witness has knowledge. The witness said he didn't have
4 knowledge. Counsel knows he doesn't have knowledge.

5 It is improper, and we would ask that he not be
6 permitted to do it with any document at this time.

7 MR. SMITH: If counsel would let -- wait to
8 object until I have laid a foundation and then -- I was
9 then going to ask him has he received it.

10 THE COURT: Is the answer to the question going
11 to be yes?

12 MR. SMITH: I don't know.

13 MR. WILLIAMS: He does know, your Honor, because
14 on page 224 of the deposition he was asked does this
15 appear to be a form letter that would be addressed to you
16 on the PCPC or list others.

17 MR. SMITH: Okay. I'll move on.

18 MR. WILLIAMS: The answer was "I have no idea."

19 MR. SMITH: I'll move on.

20 MR. WILLIAMS: Can I have a lavatory break?

21 THE COURT: Yes.

22 MR. WILLIAMS: Thank you.

23 (The following proceedings were
24 held in open court in the presence of
25 the jury:)

26 THE COURT: Folks, we've been going almost an
27 hour and a half. Why don't we take our morning recess,
28 take ten minutes or so, and then come back.

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1 The usual admonitions will apply, "admonition"
2 being the fancy word for warning.

3 (Recess taken 10:59 A.M. to 11:15 A.M.)

4 THE COURT: Back on the record with all counsel
5 here, Dr. Andersen on the stand, all jurors and both
6 alternates here. Thank you.

7 Mr. Smith.

8 MR. SMITH: May I proceed, your Honor?

9 THE COURT: You may.

10 MR. SMITH: Thank you.

11 BY MR. SMITH:

12 Q Okay, Doctor, we have about 40 minutes to lunch.
13 I've got a few more questions. Is that okay?

14 A Yes.

15 Q Thank you.

16 We were talking about, before we left for the
17 break, that you said that industry provided input into
18 the CIR on talc, and they actually wrote letters to you
19 with this input.

20 You agreed with me. Do you recall that?

21 A Yes.

22 Q Okay. And so you received letters from
23 different industry groups while at the CIR on talc during
24 the literature review; correct? The SLR?

25 A During the literature --

26 Q Don't you call it a systematic literature
27 review, SLR?

28 A Scientific literature review.

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1 Q Excuse me. Scientific literature review?

2 A When that was completed and published, it had a
3 60-day comment period, and, yes, we got comments back
4 from industry.

5 Q And so you received letters to that effect.

6 Doctor, I would like you to look at P571. I
7 mean, excuse me, EE571.

8 A Ahh.

9 Q Sorry. I can't see the letters either.
10 Are you with me?

11 A Okay. Can I see that?

12 Q Is that a letter to you?

13 A No.

14 MR. WILLIAMS: EE571, your Honor.

15 BY MR. SMITH:

16 Q Are you Dr. F. Alan Andersen?

17 A Yes.

18 Q It's April 4th, 2009. You don't see that? Are
19 we on the same page? It's a letter from the CRE.

20 A I'm sorry. I was still on 572. I apologize.

21 Q That's all right.

22 A Yes, now I do see that. That is -- yes, I do
23 see it.

24 Q You received it? It's entitled -- addressed to
25 you; correct?

26 A Yes.

27 MR. SMITH: Permission to publish EE571, your
28 Honor.

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1 MR. WILLIAMS: May I have one moment, your
2 Honor?

3 THE COURT: Yes.

4 MR. WILLIAMS: No objection.

5 MR. SMITH: Jeff, can you put up EE571? Can you
6 blow that up, Jeff?

7 BY MR. SMITH:

8 Q This is a letter from Center for Regulatory
9 Effectiveness, Bill Kelly, and it's dated August 4, 2009,
10 to you. And it says right here, "Dr. Andersen" -- well,
11 it's to you at the CIR. Do you see that?

12 A Yes.

13 "Dr. Andersen, as promised quite
14 some time ago, I'm hereby providing you
15 with a copy of the talc bibliography
16 that I've been assembling for some time
17 in the hopes that it might prove useful
18 in the CIR review."

19 You received this from the CRE; correct?

20 A Yes.

21 Q Do you know who the CRE is?

22 A As the process went on, we kind of figured out
23 what it was. When this first came in, I don't think we
24 had a sense of what it was.

25 So, yes, I understand that it is -- appears to
26 be largely an industry advocacy group.

27 Q Did you have any knowledge that the CRE was
28 hired by the PCPC regarding talc-related issues?

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1 A I didn't know that. Wouldn't have cared.

2 Q Okay.

3 MR. SMITH: Go back up to the top, Jeff.

4 MR. WILLIAMS: I'm sorry, your Honor. It was a
5 little late. Objection. Assumes facts on the last and
6 misstates prior testimony. Not from this witness, but --

7 MR. SMITH: I just asked him a question, your
8 Honor.

9 MR. WILLIAMS: Testimony from the previous
10 witness.

11 MR. SMITH: He said he didn't know.

12 THE COURT: He didn't know. Overruled.

13 MR. SMITH: May I proceed?

14 MR. WILLIAMS: Thank you, your Honor.

15 MR. SMITH: May I proceed, your Honor?

16 THE COURT: Yes.

17 MR. SMITH: Thank you.

18 BY MR. SMITH:

19 Q Bill Kelly wrote you this from the CRE; is that
20 correct?

21 A That's correct.

22 Q And you understand that he was an attorney for
23 the CRE?

24 A No. I didn't link him with the word "attorney."

25 Q Okay. But he wrote you on behalf of the CRE;
26 correct?

27 A That's correct. That's what the letterhead
28 says.

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1 Q Next, I would like to go to 567, Doctor. EE567.

2 A Okay. Yes, I have that.

3 Q Is this a letter to you -- a second letter to
4 you from the CRE?

5 A I have no idea if it's the second letter or not.

6 Q Is it a --

7 A It is another letter from the CRE.

8 Q Is it the second letter we've gone over today
9 from the CRE?

10 A Yes.

11 Q How about that? Is that okay?

12 A Yes.

13 Q Okay. Is it from -- let's go to it, Jeff.

14 MR. SMITH: Permission to publish 567, your
15 Honor.

16 MR. WILLIAMS: May I have one moment, your
17 Honor? It's a lengthy document.

18 No objection.

19 MR. SMITH: Can we pull it up, Jeff?

20 MR. WILLIAMS: Your Honor, no objection to the
21 letter itself. The attachments we may have issues.

22 BY MR. SMITH:

23 Q Well, Doctor, let me ask this: You received
24 this letter with attachments; correct? I mean --

25 A Yes.

26 Q Okay.

27 A At least I hope the attachments were included,
28 but yes.

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1 MR. SMITH: If we can blow up the top again,
2 Jeff.

3 BY MR. SMITH:

4 Q And this is Center for Regulatory Effectiveness.
5 Do you see that, Doctor?

6 A Yes.

7 Q And that's the CRE we are talking about?

8 A Yes, it is.

9 Q And then right here -- what's the date on that,
10 Jeff, 2012?

11 A Yes.

12 Q And if we can go right here, that's you; right?
13 Dr. F. Alan Andersen?

14 A That's correct.

15 MR. SMITH: And if we can go below that, Jeff,
16 right here.

17 BY MR. SMITH:

18 Q Initial Comments on CIR draft Scientific
19 Literature Review."

20 We talked about that, SLR. We used those terms
21 earlier?

22 A That's correct.

23 Q "For 'Talc as Used in Cosmetics' (posted by CIR
24 August 22nd, 2012).

25 It says in the first line here:

26 "Dear Dr. Andersen, we commend CIR
27 staff for the thoroughness of the draft
28 SLR. We do have a number of comments

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1 aimed at improving the evaluation."

2 And then he goes on for some comments.

3 MR. SMITH: And then, Jeff, if we could go to
4 page 19. It is 19 at the bottom.

5 BY MR. SMITH:

6 Q And then he says, "Respectfully, William G.
7 Kelly, Jr."

8 He doesn't have a doctor in front of his name,
9 does he?

10 A No.

11 Q "Center For Regulatory Effectiveness."

12 Do you see that?

13 A Yes.

14 Q And then he has some attachments. And I would
15 like to go to one of those. It's --

16 THE COURT: Let's not publish the attachments
17 until you indicate what they are, please.

18 BY MR. SMITH:

19 Q Okay. I would like to go to trial Exhibit
20 567-00029. It's a newspaper article regarding talcum
21 powder and ovarian cancer.

22 Do you have it in front of you, Doctor?

23 A Yes.

24 Q Are you familiar with this document?

25 A No, not particularly.

26 Q Are you familiar with this study since you did a
27 systematic review of the literature regarding talc and
28 ovarian cancer?

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1 MR. WILLIAMS: Objection. Vague and ambiguous.

2 THE COURT: Sustained.

3 BY MR. SMITH:

4 Q Are you familiar with the epidemiological
5 studies regarding talc and ovarian cancer and the basis
6 of your opinion here today?

7 A Yes. We reviewed the epidemiology studies. We
8 did not review newspaper articles.

9 Q Okay. Well, this is a 1982 publication, is it
10 not?

11 A No. It's not a publication; it's a newspaper
12 article.

13 Q Publication/newspaper article. Okay? Is it
14 1982? Is it dated 1982?

15 A Yes, it's dated 1982.

16 Q Was there a study published by Dr. Cramer in
17 1982, an epidemiological study from Harvard, that you
18 reviewed?

19 A Yes. I'm aware of the Cramer publication on his
20 epi study.

21 Q And you said you received these attachments to
22 this letter. It's addressed to you; correct?

23 A That's correct.

24 MR. SMITH: Your Honor, permission to publish
25 the article.

26 THE COURT: Any objection?

27 MR. WILLIAMS: Yes, we do have an objection.
28 It's hearsay. We would ask for an offer of proof.

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1 THE COURT: Offer the proof, Counsel, at
2 sidebar.

3 MR. SMITH: Well, I can maybe clear it up with
4 one question.

5 BY MR. SMITH:

6 Q Do you have any reason to believe that the
7 Baltimore Sun is not a reliable authority?

8 MR. WILLIAMS: Vague and ambiguous. Reliable
9 authority for what?

10 THE COURT: Sustained.

11 MR. SMITH: I'll move on.

12 BY MR. SMITH:

13 Q Are you aware of a study in 1982, Doctor, that
14 showed an increased risk of ovarian cancer from genital
15 talc use that was published by Dr. Cramer?

16 A I remember the Cramer epidemiology study. I'd
17 have to look at it to see exactly what it said about the
18 odds ratios that they found.

19 Q You don't remember that the first
20 epidemiological study done in the United States in 1982
21 by Dr. Cramer did or did not show an increased risk of
22 ovarian cancer from genital talc use and whether or not
23 it was statistically significant?

24 MR. WILLIAMS: Objection. Misstates the
25 testimony. Argumentative.

26 THE COURT: Overruled.

27 BY MR. SMITH:

28 Q You are not aware of that?

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1 A I'm aware of the Cramer study, but it remains
2 the case that the effort that the CIR expert panel did
3 was to look at all the available data. And, in this
4 case, there is no particular premise given to the first.
5 So I -- no, the first one doesn't strike me as being
6 anything. There's a whole bunch of them, and we had to
7 look at them all.

8 Q I'm not saying you didn't have to look at them
9 all; I'm just saying, based on your review -- you said
10 you looked at the epidemiological data for this case in
11 rendering your opinions; correct?

12 A That's correct.

13 Q And you can't remember whether or not the first
14 epidemiological study ever done on genital talc use and
15 ovarian cancer by the authors at Harvard, Dr. Cramer,
16 showed a statistical significant increased risk of
17 ovarian cancer from genital talc use?

18 A I'm telling you exactly that.

19 Q Okay. All right. Let's go to the next
20 document. It is E573. And if you'll flip over to the
21 second page of that, that's what I wanted to ask you
22 about. It's an email to you.

23 A This is EE573?

24 Q Yes, sir.

25 A Got it.

26 Q And if you can flip over to the second page of
27 that, it's an email exchange. Do you see down at the
28 bottom?

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1 A I'm sorry. Second page.

2 Q Yes, sir. Look down at the bottom. It's an
3 email to you.

4 A Yes, I see that.

5 Q Okay.

6 MR. SMITH: Permission to publish that portion
7 of EE573, your Honor.

8 MR. WILLIAMS: Your Honor, no objection to
9 pages 2, 3, and 4.

10 THE COURT: All right. Go ahead.

11 MR. WILLIAMS: No objection to 2, 3, and 4.

12 MR. SMITH: And, Jeff, if we can just blow this
13 up all down here.

14 BY MR. SMITH:

15 Q And this is, again, from Bill Kelly that we
16 talked about earlier from the CRE; correct?

17 A At least -- yes, the first part of it is the
18 email to me.

19 Q And it has to do with the CIR talc review. And
20 you're Alan Andersen; correct?

21 A Yes.

22 Q And it says:

23 "Dear Dr. Andersen: I know you are
24 very busy preparing for the September
25 meeting, but the talc producers and
26 users had several questions, which, if
27 possible, they would like answers to as
28 soon as possible because they have an

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1 annual meeting in San Diego next
2 Thursday. They are also highly engaged
3 in conversations on how to participate
4 in the review."

5 THE COURT: Counsel.

6 BY MR. SMITH:

7 Q Did you receive this email from the CRE, Bill
8 Kelly?

9 THE COURT: Counsel, I think you inadvertently
10 misread the last sentence.

11 MR. SMITH: I'm sorry. I apologize.

12 THE COURT: Just slow down a little here.

13 BY MR. SMITH:

14 Q Okay.

15 "They are also actively engaged in
16 conversations on how to participate in
17 the review."

18 THE COURT: Thank you.

19 MR. SMITH: I apologize.

20 THE WITNESS: Yes. I got that email.

21 BY MR. SMITH:

22 Q Okay. And I have several more here. And I
23 don't want to go waste the jury's time. But you did
24 receive similar emails, similar letters from other
25 industry groups regarding the SLR -- is that correct? --
26 or comments to it?

27 MR. WILLIAMS: I'm sorry. Just vague and
28 ambiguous as to the term "similar."

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1 THE COURT: Do you understand the question?

2 THE WITNESS: Yeah, I think I do.

3 Regarding the SLR, the factual answer is no, we
4 didn't. This is regarding preparations for the first
5 meeting at which CIR is going to talk about draft
6 reports. I'm nitpicking, but, yes, we received lots of
7 input from industry. This one related to scheduling.

8 BY MR. SMITH:

9 Q Okay.

10 A Other pieces of input related to -- one we just
11 looked at, the 19-page letter, had technical comments in
12 it. So we've gotten lots -- we had gotten lots of input.

13 Q Okay.

14 A I still say it as if I own it.

15 Q So you had a lot of input from industry
16 regarding the CIR, as we originally talked about?

17 A Well, a lot -- we got input from industry.

18 Q Okay.

19 A Not as much as we have in other cases and more
20 than in others.

21 Q Okay. I would like to go -- you discussed with
22 defense counsel the CIR on talc which came out, your
23 review; correct?

24 A I'm sorry. Say again.

25 Q The CIR on talc --

26 A Yes.

27 Q -- you reviewed; correct? You received it? I
28 mean, you talked about it with defense counsel?

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1 A Oh, yes. Sorry.

2 MR. SMITH: Your Honor, permission to publish
3 274, P274.

4 MR. WILLIAMS: No objection, your Honor.

5 THE COURT: Go ahead.

6 MR. SMITH: Thank you.

7 And, Jeff, could we pull that up, please.

8 MR. WILLIAMS: For the record, your Honor, may I
9 say that that's the same as D368.

10 THE COURT: All right. Thank you.

11 MR. SMITH: If we could go to -- Jeff, if we
12 could go to page 58 of 64. And could we go to the
13 funding section down here.

14 BY MR. SMITH:

15 Q This is the CIR final published review of talc;
16 correct?

17 A Final published review.

18 Q Yes. And it says here:

19 "The authors disclosed receipt of
20 the following financial support for the
21 research, author" --

22 Excuse me. I don't have my glasses.

23 MR. WILLIAMS: Your Honor, for the record, I
24 misspoke. This is the same as Exhibit L384.

25 THE COURT: This is the final published?

26 MR. WILLIAMS: The final final, yes.

27 THE WITNESS: The final final.

28 ///

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1 BY MR. SMITH:

2 Q Okay.

3 -- "research, authorship, and
4 publication of this article. The
5 articles in this supplement were
6 sponsored by the Cosmetic Ingredient
7 Review."

8 The Cosmetic Ingredient Review is financially
9 supported by the PCPC; is that correct?

10 A That's correct.

11 Q And earlier with defense counsel you went
12 over -- it was the expert panel -- you recall that --
13 actually, you said you sat in the room when we were in
14 the meetings but actually did the voting for talc in this
15 review?

16 A That's correct.

17 Q Okay.

18 A Procedures called for the expert panel members
19 to do the voting.

20 MR. SMITH: And I have a different number for
21 it, Mr. Williams -- it's P959 -- but it's the same
22 demonstrative that we used.

23 MR. WILLIAMS: No objection, your Honor.

24 MR. SMITH: Jeff, can you pull up 959.

25 BY MR. SMITH:

26 Q All right. This is the review panel for talc;
27 correct?

28 A That's correct.

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1 Q Expert review panel?

2 A Yes.

3 Q Who did you say Wilma Bergfeld was?

4 A She's professor of dermatology and head of the
5 dermatopathology unit at the Cleveland Clinic Foundation.

6 Q And who is Donald V. Belsito?

7 A Don is -- I don't think I said it yesterday,
8 but, because I actually know, he's the Len Harber
9 Professor of Dermatology at Columbia University.

10 Q Okay.

11 A I remember that because I knew Len Harber.

12 Q Okay. And I was looking at some publications of
13 Wilma Bergfeld. What did you say her role was now
14 regarding the Cosmetic Ingredient Review and talc?

15 A Wilma was the chair of the expert panel.

16 Q So she was the chair.

17 Give me one second, Doctor.

18 And I saw a publication of -- or she was --
19 first of all, do you know if Dr. Bergfeld regularly gives
20 talks and presents at, for instance, the American Academy
21 of Dermatology? Are you familiar with that?

22 A Yes.

23 Q Okay. And the American Academy of Dermatology,
24 that's a reputable outfit; correct?

25 A In my view.

26 Q Okay.

27 MR. SMITH: Your Honor, permission to publish

28 958 -- P958.

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1 MR. WILLIAMS: 958 is not in my notebook.

2 MR. SMITH: It's in the second notebook. I'm

3 sorry. Hold on.

4 THE WITNESS: I have -57 and -59.

5 MR. SMITH: Hold on.

6 May I approach, your Honor?

7 THE COURT: Yes.

8 MR. SMITH: Here you go, your Honor. You have
9 it?

10 THE COURT: I do.

11 MR. SMITH: Permission to publish P958.

12 MR. WILLIAMS: Lacks foundation to the witness,
13 your Honor.

14 MR. SMITH: Your Honor, he is familiar with the
15 American Academy of Dermatology and that Dr. Bergfeld
16 would give talks.

17 THE COURT: Lay a foundation before you publish
18 this.

19 MR. SMITH: Okay.

20 BY MR. SMITH:

21 Q Let me ask you this, Doctor: Any of the expert
22 panel review, do you check them for conflicts of
23 interest?

24 A That's correct.

25 Q And so they should not be receiving payments or
26 an expert or have any type of disclosure of a conflict of
27 interest with industry; correct?

28 A The cosmetics industry, yes.

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1 Q And did you check that, or did they voluntarily
2 do that?

3 A They provide that information to me.

4 Q Do you double-check it?

5 A No, I don't really.

6 Q Okay. To the best of your knowledge, did any of
7 the expert panel review on talc and ovarian cancer have
8 any conflicts of interest?

9 A No.

10 MR. SMITH: Permission to publish 958, your
11 Honor.

12 MR. WILLIAMS: Still lacks foundation to the
13 witness.

14 THE COURT: It does, and I don't know what the
15 date of it is, what year it is.

16 MR. SMITH: Your Honor, to be honest with you,
17 whether it's before or after, I think it has the same
18 effect.

19 THE COURT: I disagree with that, Counsel. Lay
20 a foundation for this. If you don't have a foundation,
21 you may not publish it.

22 BY MR. SMITH:

23 Q Well, do you have any reason to believe that the
24 American Academy of Dermatology is not a reliable or
25 authoritative source of information?

26 MR. WILLIAMS: Objection, your Honor. Lacks
27 foundation to the witness. Plus irrelevant for this
28 purpose and no foundation for the witness.

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1 THE COURT: Overruled.

2 MR. SMITH: Thank you.

3 BY MR. SMITH:

4 Q Do you have any reason to doubt that they are an
5 authoritative, reliable source of information?

6 A No, I don't.

7 MR. SMITH: Permission to publish P958, your
8 Honor.

9 MR. WILLIAMS: Same objection. Relevance hasn't
10 been laid, your Honor.

11 THE COURT: Sustained.

12 BY MR. SMITH:

13 Q If any of the expert panel for the talc and
14 ovarian cancer for the CIR had any conflict of interest
15 of working for the defendants or receiving money for the
16 defendants, is that information that you would know
17 today?

18 A Yes. That would be information that the -- in
19 my role as director of CIR I would want to have.

20 MR. SMITH: Permission to publish 958, your
21 Honor.

22 MR. WILLIAMS: Lacks foundation, your Honor.

23 THE COURT: Sustained.

24 BY MR. SMITH:

25 Q Okay. Let's go to Donald Belsito. He was on
26 the -- Belsito; correct?

27 A Belsito, yes.

28 Q Belsito. Do you know whether he was receiving

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1 any payments from the defendants during the time period
2 that he was sitting on the expert panel for the CIR
3 review for the safety of talc?

4 A Any payments --

5 Q Yes.

6 A Boy, I would have to go back -- I don't have
7 access to. All of the scientists on the panel on
8 occasion, like Dr. Bergfeld, would give scientific
9 presentations. And those scientific presentations often
10 were sponsored by industry. So could Don have made a
11 presentation on his work and been supported by industry?
12 Yes, it's possible.

13 He would have told me about that, and I would
14 have given a thumbs-up or thumbs-down to each of the
15 circumstances, as I had done for Dr. Bergfeld.

16 Q So you're saying you gave a thumbs-up for
17 Dr. Bergfeld? Is that what you just said?

18 A Yes. The -- if you would focus on -- I don't
19 know. Can we put that P958 back up.

20 Q Your counsel didn't want it to be shown.

21 MR. WILLIAMS: First of all, I'm not his
22 counsel, your Honor. Second of all, that's an improper
23 statement by counsel.

24 THE COURT: It is improper, but --

25 MR. SMITH: Excuse me.

26 BY MR. SMITH:

27 Q I was not allowed to show the document, Doctor.
28 So I want to ask you.

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1 A Oh, I thought you did. I'm sorry.

2 Q I was trying to.

3 My question is, so you recall now giving
4 Dr. Bergfeld a thumbs-up regarding a conflict of interest
5 that she had during the CIR review of talc with the
6 defendants Johnson & Johnson?

7 A As the conduct of CIR business, every seminar
8 that a CIR member gave that involved industry sponsorship
9 or was to an industry group was brought to me and cleared
10 as to whether this actually presented a conflict of
11 interest. There's no question that the support existed.
12 If you are going to Johnson & Johnson to give a seminar,
13 there's no question it's Johnson & Johnson, but the
14 question of whether this represented a conflict of
15 interest, in my view, it didn't.

16 Q Okay. So you were aware that Dr. Bergfeld, the
17 leader of the CIR on the expert panel that had a vote on
18 whether talc was safe or not, you had knowledge had a
19 conflict of interest of receiving money from Johnson &
20 Johnson during the time that she's reviewing it and you
21 said, in your judgment, thumbs-up?

22 MR. WILLIAMS: Misstates testimony, your Honor.

23 MR. SMITH: I think it's pretty accurate.

24 THE WITNESS: No, it's not accurate. I said it
25 did not represent a conflict of interest.

26 BY MR. SMITH:

27 Q Correct. Thumbs-up?

28 A She went to talk about her research on alopecia,

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1 hair loss in women. That's her major area of research.
2 I did not consider that a conflict of interest with the
3 CIR's review of cosmetic ingredients. She was giving a
4 medical paper.

5 Q Sir, the lead expert panelist, you had knowledge
6 of, was receiving money from the defendants who -- one of
7 their major products is at issue in the CIR review, and
8 you did not -- is it disclosed anywhere in this review?

9 A I'm sorry. Is -- is what disclosed? The fact
10 that she received that money?

11 Q Yes, sir.

12 A No, it's not.

13 Q Right. And I'd like to go to 274 to go to the
14 conflicts of interest -- excuse me -- declaration of
15 conflicts of interest.

16 MR. SMITH: Can we go to 274, Jeff.

17 It has been previously put before the jury, your
18 Honor.

19 MR. WILLIAMS: Is it P274?

20 MR. SMITH: Yes.

21 THE COURT: P274, that's the final CIR report.

22 MR. WILLIAMS: Thank you.

23 MR. SMITH: Get my glasses on so I can see what
24 all is going on.

25 All right. Let's go to the declaration of
26 conflicts of interest, Jeff.

27 BY MR. SMITH:

28 Q Okay.

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1 "The authors declare no potential
2 conflicts of interest with respect to
3 research, authorship, and publication of
4 this article."

5 A That's correct.

6 Q So there's no mention -- so if this goes out to
7 the general public, we come into court in front of a
8 jury, or any other scientist in the world looks at this
9 paper, they do not know that the lead expert panelist
10 reviewing the safety of talc was receiving money from
11 Johnson & Johnson during the time that this publication
12 is being authored; correct?

13 A I don't know about the part of your statement
14 relating to "during the period of time." But I will
15 acknowledge that the existence of financial support for
16 her medical research existed, and I didn't consider that
17 a conflict of interest with the work being done by CIR.
18 And that's how it was captured in the declaration.

19 Q You didn't consider it a conflict of interest,
20 according to Dr. Andersen, who's on the payroll for
21 \$300,000 a year, determined that --

22 A It was my --

23 Q -- being funded by them?

24 A -- responsibility to make that determination,
25 yes.

26 Q Did you run it by anybody?

27 MR. WILLIAMS: Objection, your Honor.
28 Argumentative. I really think it's inappropriate.

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1 THE COURT: It's compound. Which question would
2 you like him to answer?

3 MR. SMITH: Yes, your Honor.

4 BY MR. SMITH:

5 Q Did you run it by anybody?

6 A No. I was the director of the Cosmetic
7 Ingredient Review.

8 Q You got paid \$300,000 a year partly by these
9 defendants that had the conflict of interest with the
10 head expert panel reviewer?

11 MR. WILLIAMS: Argumentative. Assumes facts.

12 THE COURT: Overruled.

13 THE WITNESS: My determination was that there
14 wasn't a conflict of interest.

15 BY MR. SMITH:

16 Q Okay. Do you think that's information that a
17 scientist, me, the jury, or anybody that's going to look
18 at this paper and not understand all that's going on give
19 to decide what weight I want to give this, don't you
20 think that's important information to put in the
21 declaration of the conflicts of interest?

22 A No.

23 Q Okay. All right. What about Dr. Donald
24 Belasito? You said you were aware that he was doing some
25 talks during this time.

26 And can we pull up that expert panel again,
27 Jeff. What is it? P -- Jeff, it's P959.

28 All right. So we talked about the lead -- what

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1 was her title again? The what of the expert panel
2 review?

3 A Wilma Bergfeld was the chair of the CIR expert
4 panel.

5 Q Okay. And I mispronounced the name. Sorry.
6 Donald V. Belsito; is that right?

7 A That's correct.

8 Q Okay. What payments were you aware that
9 Johnson & Johnson was giving him during the time that
10 this expert panel was reviewing the safety of talc for
11 which is the main ingredient in baby powder?

12 MR. WILLIAMS: Lacks foundation and assumes
13 facts, your Honor.

14 MR. SMITH: He has already talked about that he
15 was aware of it and he didn't determine it was a conflict
16 of interest, your Honor.

17 THE COURT: Overruled.

18 MR. SMITH: Thank you.

19 THE WITNESS: I don't have a recollection of a
20 specific list or item. What I do recall is the standard
21 operating practice, which is, on a regular basis, I got
22 requests from the members of the expert panel, "I want to
23 give this seminar." Many of them were at the Academy of
24 Dermatology meetings and talked about their professional
25 work. And I would either approve it or not approve it.

26 BY MR. SMITH:

27 Q Were you aware of payments, like Ms. Bergfeld --
28 excuse me -- Dr. Bergfeld, Dr. Belsito was receiving from

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1 Johnson & Johnson and their subsidiary Janssen Biotech
2 during the time that he sat on review on the CIR for the
3 safety of talc? Did you give that a thumbs-up and
4 thumbs-down like you did for Dr. Bergfeld?

5 A As it would -- again, I don't remember specific
6 details, but, as a pattern, if his medical research was
7 being sponsored, then that was not considered a conflict
8 of interest with his review of cosmetic ingredients.

9 Q According to Dr. Andersen?

10 A That's the way I implemented it, yes.

11 Q Okay.

12 MR. SMITH: Let's go back to -- Jeff, can we go
13 to P274.

14 Your Honor, it's the safety assessment of talc
15 that we've been talking about, the CIR. Can I publish
16 some other parts of that, please?

17 THE COURT: Go ahead.

18 MR. SMITH: Thank you.

19 BY MR. SMITH:

20 Q I want to go -- this is a thick document, and
21 it's got a lot of footnotes to scientific literature
22 that's cited in the body of the paper; correct?

23 A I don't know that there are very many footnotes.

24 Q Well, I counted 218, whatever it is. If you
25 want to say that's not many; it is. It's 218.

26 Do you recall that?

27 A Those are not footnotes. I mean, I don't mean
28 to nitpick, but those are reference citations. I believe

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1 there was a couple of footnotes on the first page,
2 numbering four.

3 Q Can we agree there are 218 citations --

4 A Yes.

5 Q -- to scientific literature that's in the body
6 of the CIR?

7 A Yes.

8 Q Okay.

9 I would like to go to -- can we go to page 63 of
10 64, Jeff, and focus in on Number 177.

11 "W.G. Kelly, initial comments on
12 CIR draft scientific literature review
13 for talc. Talc as used in cosmetics
14 posted by CIR, Aug. 22, 2012, letter
15 report submitted to Andersen F.A. by
16 Kelly W.G., 2012."

17 Do you see that?

18 A Yes.

19 MR. SMITH: Then, Jeff, if we can flip over to
20 where that citation references, which is page 33 of 64.
21 And if we can go to that second paragraph, Jeff, right
22 here.

23 BY MR. SMITH:

24 Q Okay.

25 "The possibility that using
26 cosmetic talc powder can cause ovarian
27 cancer was suggested when talc particles
28 were found on human ovarian tissues.

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1 The translocation of talc particles from
2 the perineum to the ovaries would
3 require that these particles pass from
4 the perineum through the vagina and the
5 cervical canal, move across the uterus
6 and against the ciliary motion of the
7 Fallopian tubes across the peritoneal
8 space between the fimbriae and ovaries,
9 escape phagocytosis in the peritoneal
10 space, and attach to the surface of the
11 ovaries to accumulate in the ovaries."

12 And there is the Citation 177; correct?

13 A And 178.

14 Q And 178; right?

15 A Yes, it is.

16 Q We just went through the letters of Bill Kelly
17 from the CRE to have input into the CIR. And he's an
18 attorney for the CRE that you're quoting for this
19 scientific conclusion?

20 MR. WILLIAMS: Assumes facts, your Honor.

21 THE COURT: Sustained.

22 BY MR. SMITH:

23 Q Is this not a scientific -- are these not
24 scientific terms and conclusions here that I just read to
25 you? Are they legal conclusions?

26 A I'm not sure in -- just exactly how to answer
27 your question. The CIR expert panel determined that this
28 information should be included in the report. The

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1 information came from two different sources. And, as
2 part of our process, we make even the unpublished data
3 from the CRE available and part of the package. If the
4 panel concludes that that information is independently
5 verified by itself, then it puts it in. But because it
6 came from a lawyer -- which I don't think they knew --
7 but whether it did or didn't, it's the information that
8 the panel focuses on, not the source.

9 Q The source is a lawyer from the CRE who was
10 hired as a consulting group for the PCPC for which these
11 defendants are a member of; correct?

12 MR. WILLIAMS: Your Honor, assumes facts.

13 THE COURT: Sustained.

14 BY MR. SMITH:

15 Q Do you know that to be true?

16 A Do I know what to --

17 Q The CRE was an industry trade group that -- we
18 discussed earlier --

19 A Yes, that, I know.

20 Q Okay. They're hired by the PCPC?

21 A I don't know that they were hired by the PCPC.
22 That part I guess I don't know.

23 Q Were they consultants for the PCPC?

24 A I really don't know that.

25 Q You don't remember the conversation we had
26 earlier about the CRE and Bill Kelly? We went through
27 the two letters I showed the jury? Do you not recall
28 that?

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1 A I recall looking at a letter from CRE to me
2 and -- giving comments on the SLR. I recall the email
3 from Bill Kelly on procedures and process. I'm just
4 not -- I don't recall anything that told me that he was a
5 consultant or that that group was consulting with PCPC.
6 And I could just be misremembering. I just don't
7 remember that specifically.

8 Q In any event, he's a --

9 A But it's an industry group. There's no
10 question.

11 Q Okay. He consulted for an industry group;
12 right?

13 A Well, CRE is an industry group, yeah.

14 Q Correct. Okay.

15 Well, you're not a consulting company in an
16 industry group if you're not consulting for industry;
17 right?

18 All right. We'll leave it at that.

19 I'll tell you what, Bill Kelly is a lawyer at
20 the CRE who's cited on 177 in the CIR review; correct?

21 A That's correct.

22 MR. WILLIAMS: That's mis- --

23 MR. SMITH: That's all the questions I have at
24 this time -- well, not for this witness, but before
25 lunch, if you want to take a break, your Honor. I'm
26 getting ready to move to another topic.

27 THE COURT: Okay. Maybe this would be a good
28 time for lunch.

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1 Let's take our recess for the noon hour.

2 Everybody leave your notes here. Have a good lunch.

3 Don't discuss the case. Don't do any research. Wait

4 until you hear all the evidence before you form any

5 opinions. Have a nice lunch.

6 (Jury leaves the courtroom.)

7 (The following proceedings were

8 held outside the presence of the jury:)

9 THE COURT: You can step down, sir. Thank you.

10 Is everybody good until 1:30?

11 MR. SMITH: Yes, your Honor.

12 MR. WILLIAMS: Yes.

13 THE COURT: Okay.

14 (Whereupon, the matter was adjourned for

15 lunch at 11:58 A.M. and to be resumed at

16 August 11, 2017, at 1:30 P.M..)

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August 11, 2017

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

3

FOR THE COUNTY OF LOS ANGELES

4

5

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

6

7

COORDINATION PROCEEDING,)

SPECIAL TITLE (RULE 3.55))

8

) JCCP NO. 4872

)

9

JOHNSON & JOHNSON TALCUM) REPORTER'S

POWDER CASES,) CERTIFICATE

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15

I, Pamela Cotten, CSR NO. 4497, pro tem reporter of
the Superior Court of the State of California, for the
County of Los Angeles, do hereby certify that the
foregoing pages, 3205 - 3329, comprise a full, true and
correct transcript of the proceedings and testimony taken
in the above-entitled cause on August 11, 2017.

21

22

Dated this 11th day of August, 2017.

23

24

25



PAMELA COTTEN, CSR, NO. 4497

26

OFFICIAL PRO TEMPORE REPORTER

27

28

Exhibit 123



MATERIAL DATA SAFETY SHEET

TALC

Section 1. Product and Company Identification						
Product Names	IMPERIAL 200 USP		IMPERIAL 500 USP		OLYMPIC H USP	GRADE 25 USP
	IMPERIAL 250 USP		IMPERIAL 700 FCC		SUPREME H USP	
	IMPERIAL 400 USP		SUPRA H USP		SUPRAFINO H USP	
Synonyms	Talcum powder, Soapstone, Steatite					
Chemical Name	Talc ; Hydrous magnesium silicate		CAS#	14807-96-6	Chemical Family	Phyllosilicates
Manufacturer	Luzenac America, Inc.		Emergency Health			
	345 Inverness Drive South		Information (24 hrs)			
	Centennial, CO 80112		303-623-5716			
	Toll-free 800-325-0299					

Section 2. Composition/Information on Ingredients			
Substance	CAS#	% by Weight	TLV - TWA
Talc	14807-96-6	98-100	2 mg/m3 respirable fraction (ACGIH)
Dolomite	16389-88-1	0-2	Use Talc TLV for total exposure measurements

Section 3. Health Hazards Identification and Emergency Overview	
Emergency Overview	Under normal conditions of use, this product is not expected to create any unusual emergency hazards. This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point, and poses NO special hazards in the presence of fire.
<p style="text-align: center;">Potential Health Effects from Acute and Chronic Occupational Exposures to Talc</p> <p style="text-align: center;">TARGET ORGANS</p> <div style="text-align: center;"> <p>LUNGS, RESPIRATORY SYSTEM</p> </div>	
Inhalation	<p>ACUTE: Exposure to a large concentration of air-born dust of this material may cause mechanical irritation of the mucous membranes and respiratory tract.</p> <p>CHRONIC: Repeated or prolonged inhalation of air-born dust of this material may cause scarring of the lungs (pulmonary fibrosis), with shortness of breath, chronic cough, and respiratory assisted heart failure. Prolonged exposure to talc can produce symptomatic talc pneumoconiosis (talcosis).</p>
Skin Contact	<p>ACUTE: Direct contact may cause dryness, or may cause mild irritation if an allergic predisposition exists.</p> <p>CHRONIC: Prolonged contact may cause dryness of the skin, or may cause mild irritation if an allergic pre-disposition exists</p>
Eye Contact	<p>ACUTE: Direct contact with dust may cause mechanical irritation of the eyes.</p> <p>CHRONIC: Repeated exposure may cause conjunctivae inflammation.</p>
Ingestion	<p>ACUTE: This material is considered to be harmless and inert when ingested.</p> <p>CHRONIC: Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results.</p>

Luzenac America, Inc.
MSDS Group USP
Issued 07/01/2006

Talc
CAS #14807-96-6
Page 1 of 5

Section 4. First Aid Measures

Inhalation	Remove from exposure area to fresh air. If breathing has stopped, perform artificial respiration and get medical attention immediately. Keep person warm and at rest. Treat symptomatically and supportively.
Skin Contact	Apply common skin moisturizers to relieve dryness. Irritations are uncommon; however, if irritation or redness develops, seek medical attention. Broken skin can be cleansed with mild soap and water.
Eye Contact	Wash eyes with large amounts of water or normal saline solution. If irritation or redness develops, seek medical attention.

Section 5. Fire Fighting Measures

Flammability	This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point, and poses NO special hazards in the presence of fire. Firefighters require NO special protective equipment or precautions.
--------------	--

Section 6. Accidental Release Measures

Small Spill	Use vacuum to clean up spillage. Place in sealed container.
Large Spill	For large spills, shovel or sweep up (while keeping dispersion of dust in air to a minimum) and place into suitable sealed containers for reclamation or later disposal. Residue should be cleaned up using a high-efficiency particulate filter vacuum. The use of water wash-down is not recommended. Wet material can cause a surface used for walking to become extremely slippery. Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261).

Section 7. Handling and Storage

Handling & Storage	Handle in ways to minimize the creation of dust. Preserve product in sealed containers.
--------------------	---

Section 8. Exposure Controls & Personal Protection

Personal Protection	Use NIOSH approved dust respirator. Use safety glasses or dust tight goggles. No special skin protection is usually required, but gloves should be worn by workers susceptible to skin irritation.
---------------------	--



Controls	Provide local exhaust or process enclosure ventilation to meet published exposure limits (TLV).
----------	---

Section 9. Physical & Chemical Properties

Appearance	White to grayish-white powder
Odor	Slight earthy odor.
Flammability	This product is NOT flammable, NOT reactive, NOT explosive, has NO flash point.
Specific Gravity	2.8 (water = 1.0)
Melting Point	None
pH	Slightly basic (10% slurry in water)
Solubility	Water: <1 mg/mL @ 21 C Acetone : <1 mg/mL @ 21 C

Ethanol: <1 mg/mL @ 21 C

Cold acids: Insoluble

Alkalies: Insoluble

Section 10. Stability & Reactivity Data**Stability** This product is stable, non-reactive, and non-corrosive.**Incompatibility with various substances** Non reactive/none known.**Section 11. Toxicological Information**

Toxicology NIOSH Registry Number: WW2710000
 SAX Toxicity Evaluation: THR: Not available
 Carcinogenic Status:
 IARC: (2006 in preparation) Has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only.
 IARC: (2006 in preparation) Inhaled talc not containing asbestos or asbestiform fibres not classifiable as a human carcinogen (Group 3)
 OSHA: Not listed.
 ACGIH: A4 – Not Classifiable as a Human Carcinogen
 NTP: Not listed. A 2-year inhalation study demonstrated clear evidence of carcinogenic activity in female rats at exposure levels of 18 mg/m³. Some evidence of carcinogenic activity was observed in male rats at the same level. No evidence of carcinogenic activity was found in mice (NTP TR-421).
 Tumorigenic Data:
 TClO: ihl-rat 11 mg/m³/1Y-I
 TDLo: imp-rat 200 mg/kg
 Other Toxicity Data:
 Skin and Eye Irritation Data: skn-hmn 300 ug/3D-I MLD
 Teratogenicity (Reproductive Effects Data): Not available.
 Mutation Data: Not available.

Section 12. Ecological Information**Ecological Data**

Species Test	Alga ((<i>Selenastrum capricornutum</i>))	<i>Daphnia Magna</i> Acute immobilization	<i>Daphnia Magna</i> Reproduction
Endpoint	Growth rate 48hr-EC50 48hr-NOEC AUG 72hr-EC50 72hr-NOEC	48hr-EC50	21 day-EC50 21 day-NOEC
Conc. (mg/L)			
FY			
References			

*AUG=Area Under Growth curve

Section 13. Disposal Considerations

Waste Disposal Information Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). Dry material can usually be land-filled. State and Local regulations/restrictions are complex and may differ from Federal regulations. Responsibility for proper waste disposal is with the owner of the waste.

Section 14. Transport Information

Transport Information U.S. Department of Transportation - DOT: No classification assigned
 CANADIAN Transportation of Dangerous Goods: No classification assigned
 LAND Transport - ADR/RID: No classification assigned
 AIR Transport - IATA/ICAO: No classification assigned (International Air Transport Association/International Civil Aviation Organization)
 MARITIME Transport - IMDG: No classifications assigned International Maritime Dangerous Goods)
 HARMONIZED Tariff Code: Talc – crushed or powdered. 2526.20.00. (Stat. Suffix 00)
 EPA TSCA 12(B) Export Notification: Not listed

Section 15. Regulatory Information

Chemical Inventories EPA TSCA Status: Listed (CAS # 14807-96-6) EINECS (European No: 238-877-9)
 CEPA Domestic Substance List – DSL: Listed CEPA Non-domestic substance List – NDSL: Not listed
 AICS (Australian – NICNAS) ECL (Korean No: KE-32773)
 SWISS (Giftlist No: G-6939) PICCS (Philippines)
 ENCS/MITI (Japan) – Talc exempt IECSC (China): Listed

Other Pertinent Classifications/Regulations

CALIFORNIA PROP 65 Status: Talc not listed
 STATE RIGHT-TO-KNOW: Talc listed – Illinois; Massachusetts; New Jersey; Pennsylvania; Florida
 CLEAN AIR ACT – Ozone Depleting Chemicals (ODC's): None
 CONEG Approved Packaging: Yes
 NFPA RATINGS: (Scale 0-4) Health = 1, Fire = 0, Reactivity = 0

NPCA: National Paint and Coatings Association – Hazardous Material Identification System (HMIS)

HEALTH: 1* (Chronic Potential)

FLAMMABILITY: 0

PHYSICAL: 0

PERSONAL PROTECTION: dust respirator, glasses or goggles, gloves

Section 16. Other Information

Label Hazard Warning CAUTION - PROLONGED EXCESSIVE INHALATION MAY CAUSE LUNG INJURY

Label Precautions UTILIZE DUST RESPIRATOR AND EXHAUST VENTILATION. REFER TO MSDS FOR COMPLETE DETAILS



TYPICAL APPEARANCE OF PRODUCT LABEL

Primary References ACGIH - Documentation of TLV's 2001
 OSHA - Chemical Sampling Information: Talc (Containing no asbestos) (Revised 1/15/1999)

for Key Data	<p>OSHA - TALC (Containing no asbestos). OSHA comments from the June 19, 1988 Final Rule on Air Contaminants Project extracted from 54FR2324 <i>et. seq.</i></p> <p>OSHA - Compliance Interpretation Letter dated August 22, 2000 regarding talc products containing less than 1% quartz.</p> <p>OSHA - Guidelines for Employer Compliance (Advisory) 1910.1200 App E</p> <p>NIOSH - Pocket Guide to Chemical Hazards. Talc (containing no asbestos and less than 1% quartz).</p> <p>NIOSH - REL's and General Recommendations for Safety and Health. [TALC (containing no asbestos).</p> <p>AIHA - Hygienic Guides Series – Talc (1982)</p> <p>IARC - Talc Vol.: 42 (1987) (p.185) 5. Summary of Data Reported and Evaluation; Supplement 7: (1987) (p.349) Talc Not Containing Asbestiform Fibers (Group 3).</p> <p>CCOHS – Database MSDS FTSS. Network Version 2002.</p> <p>NTP – RoC/NIEHS Database. Network Version 2002.</p>
Glossary	<p>ACGIH – American Conference of Governmental Industrial Hygienists</p> <p>AIHA – American Industrial Hygiene Association</p> <p>CCOHS – Canadian Centre for Occupational Health and Safety</p> <p>IARC – International Agency for Research on Cancer</p> <p>NIOSH – National Institute of Occupational Safety and Health</p> <p>NTP – National Toxicological Program</p> <p>OSHA – Occupational Safety and Health Association</p> <p>PEL – Permissible Exposure Level</p> <p>TLV – Threshold Limit Value</p> <p>TWA – Time Weighted Average</p>
Important Notice	<p>Luzenac America, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.</p>
Issued by	<p>Richard J. Zazenski Regulatory Affairs Manager E-mail: rich.zazenski@america.luzenac.com Phone: 1-303-643-0404 Fax: 1-303-643-0446</p>

Exhibit 124

[Letter of proposal to FDA and NIEHS/NIH]

The FDA has legislative responsibility for direct regulation of unsafe ingredients in cosmetics under the Food, Drug and Cosmetic Act. In 1994, as a result of concerns regarding the 1993 NTP animal study and recently published epidemiological studies linking talc and ovarian cancer, the FDA and the International Society for Regulatory Toxicology and Pharmacology co-sponsored a workshop to discuss the issues and to see whether they could arrive at any consensus views on how they should be interpreted. Twenty FDA scientists participated, along with numerous scientists from academia, industry, cancer research institutions, NIEHS, NCI, and other organizations.

At the beginning of the workshop, Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, presented the "Introduction: Overview - Scope of the Workshop", in which he stated:

“ . . . I think it is reasonable to expect by the end of the workshop to have a discussion or even to reach a consensus of the many scientific and medical experts that are participating in and attending this meeting about the relevance of the recent reports to the safety of talc to human health risks.”

At the conclusion of the Workshop, an Executive Summary was prepared by the Rapporteur, Dr. Jelleff Carr (Talc: Consumer Uses and Health Perspectives" in *Reg. Tox. Pharm.* 21(2):211-60 (1995). With regard to the ovarian cancer issue, Dr. Carr explains the consensus that was reached:

“Following the many issues raised by all presenters, the ensuing discussion generally agreed that while some weak association between talc exposure and ovarian tumors has been reported, it was not sufficient warning for concern.”

“The possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health importance. However, this association remains a research hypothesis whose verification or falsification needs additional study.”



“[E]pidemiologic studies have provided weak and conflicting risk signals for this association and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures.”

Indeed, the prediction by the panel that additional epidemiology studies on this subject would prove inadequate to clearly define an association between the perineal application of talcum powder and an increased risk of ovarian cancer was accurate. When NTP began their review of non-asbestiform talc in 2000, eight additional epidemiologic studies were published and evaluated by NTP. The eight additional studies continued to provide weak and conflicting risk signals with no consistent trend by duration or frequency of talc use. Appropriately, the NTP Board of Scientific Counselors Subcommittee concluded that the listing of cosmetic talc was not scientifically justified and voted 7-3 not to list talc (not containing asbestiform fibers).

Since the conclusion of NTP review in 2000, only one additional case-control study has been published (Central Valley of California). Not surprisingly, this additional epidemiological study provided no new information of scientific utility.

Given all this scrutiny during the last decade of “cosmetic talc” and its association with ovarian cancer, Luzenac cannot imagine that an additional review by NTP would result in a reversal of consensus about the scientific validity of this hypothesized association. But given the sensitive nature of this very serious women’s health issue and the lingering suspicions concerning cosmetic talc as a possible risk factor, Luzenac would like to propose a remedy to FDA and NIEHS/NIH that would eliminate the need for any further debate and review of this issue.

We propose:

1. The talc industry in the United States will voluntarily phase-out the production and sale of all cosmetic talc products used specifically for consumer dusting powders, body powders, baby powders, and any other loose powder products that might reasonably be anticipated to be used by women for perineal application.

2. In cooperation with domestic cosmetic and pharmaceutical member companies of the CTFA, this product phase-out will occur within XX months of acceptance of these proposals by NTP and FDA.
3. The voluntary withdrawal would not include such products as medicated foot powders where it would not be reasonably anticipated that the product would be used for perineal dusting; nor would the withdrawal include cosmetic talc products sold for make-up, lipstick, eye-shadow and cream foundations where it would not be reasonably anticipated that the product(s) would be used for perineal dusting.
4. The CTFA will assist the FDA in developing an appropriate cosmetic warning label for any dusting or body powders containing talc which are produced or imported after an established date. The label would warn the consumer the product is not to be used for genital dusting and would report of the possible association between genital dusting and ovarian cancer. The warning label would be mandatory.

The result of these proposed actions would:

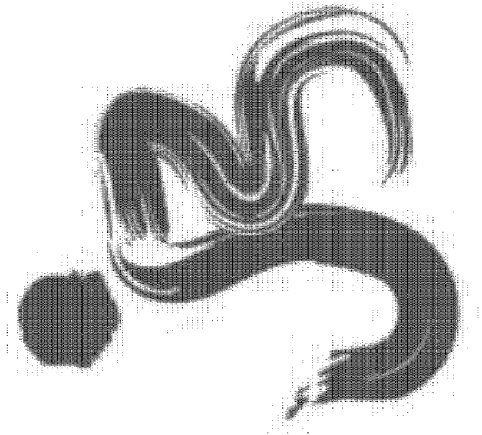
1. In very short order, virtually eliminate the exposure potential in the general population to dusting powders containing talc. As more and more dusting powders have already been re-formulated with increased levels of cornstarch, the proposed actions would accelerate these product conversions.
2. Eliminating the perineal exposure potential for women suspends the need for NTP to proceed with a review of cosmetic talc. Given the weakness of the science, it is improbable that a listing recommendation would have resulted – meaning the debate on this theorized association would continue unresolved. These voluntary actions proposed by the talc industry and CTFA member companies would end the debate and allow researchers to focus on other more plausible risk factors.

IMERY S284935

Metadata

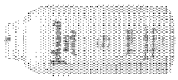
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Custodian	Zazenski, Rich;	ORIGINAL
DateCreated	11/30/2004 9:03 PM	ORIGINAL
OtherCustodians	Zazenski, Rich;	ORIGINAL

Exhibit 125

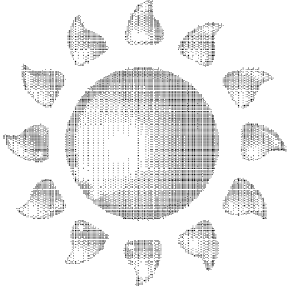


JOHNSON'S® Baby Powder
2010 Media Recommendation





2010 Powder Program Overview



Objective:

- Recruit new and younger users by giving them a compelling reason to use JOHNSON'S® Baby Powder

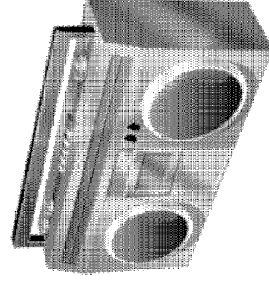
Key Strategies and Tactics:

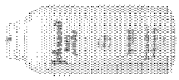
- Target overweight women living in hot climates during key summer season
- Launch campaign with an insertion in People Magazine within weight loss edit and use Weight Watchers Magazine and Everyday with Rachael Ray to target women who are overweight
- Utilize local or geo-targeted media in hot markets that have a high percentage of overweight consumers

Budget: \$555.2M (+12%)

Timing: Q2-Q3

Media Mix: Print: 47%; Radio/Digital: 53%





2008/2009 Programs targeted “Women with Curves”

Historic target exhibited distinct behaviors that allowed JOHNSON’S® to reach her easily

- Print in Weight Watchers Magazine
 - Print out-performed norms for Weight Watchers magazine
 - Advertisements explained alternate usages
- Digital on diet sites
 - Digital banners slightly exceeded benchmarks with a .15% CTR
 - Hub on WeightWatchers.com to increase relevance of messaging vs. brand page, resulted in about 24,000 visits
- Sampling at gyms and walking events

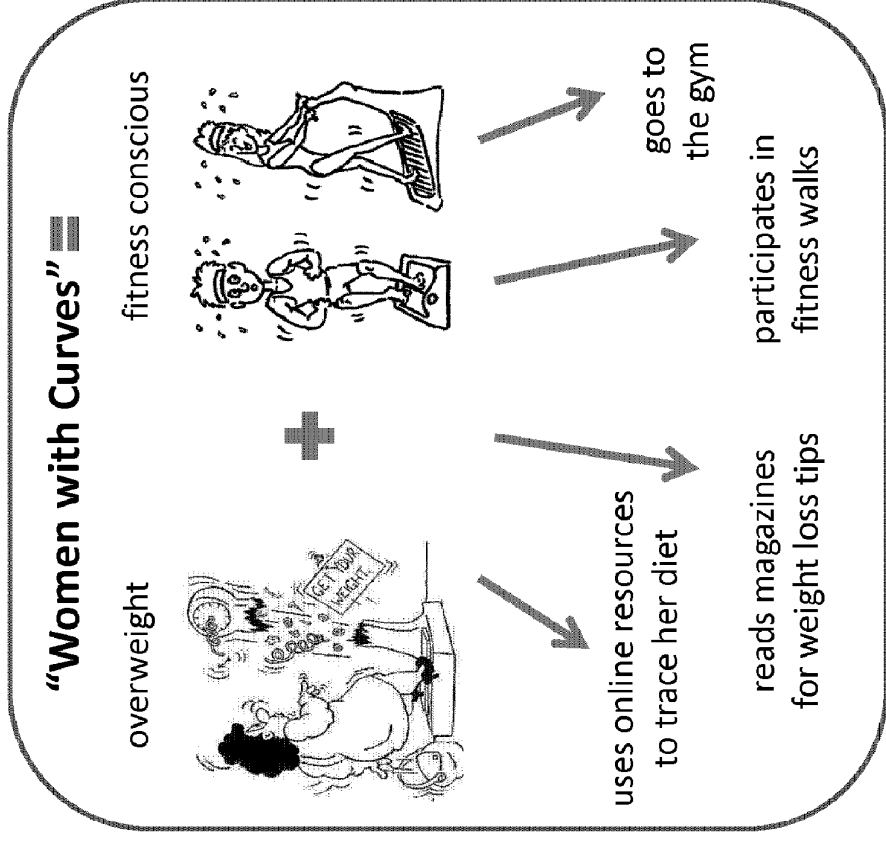


Exhibit 126



Definition: *License* - to permit, authorize,
allow, certify.....

You want to drive? – You need to learn the rules and obtain a license.

You want to fish? – You need to learn the rules and obtain a license.

You want to get married? - You need to learn the rules (???) and obtain a license.

You want to market a product? – You need to learn the rules; and while you do not obtain an official marketplace license, a change in the rules can have a material effect on your ability to market your product.



2









What do we need to do to protect our license to market?

- Retain internal regulatory expert(s)
- Closely (and regularly) monitor regulatory and agency activities
- Utilize Internet tools e.g., “Google News Alerts”
- Establish and maintain ties with outside resources e.g., expert legal counsel, “watchdog” services (Center for Regulatory Effectiveness), medical experts with knowledge of your product, legislators, policy makers



6

Exhibit 127

Litigation Issues

- February 26, 2002 -

General Stages of a Civil Complaint – United States

1. SERVICE OF THE COMPLAINT

- I. Engage Counsel Licensed in State
- II. File Formal Response to all Charges with Court

2. DISCOVERY PROCESS

- I. Interrogatories
- II. Request for Documents
- III. Depositions
- IV. Expert Witness Designation & Reports
- V. Request for Admissions
- VI. Pre-trial Conference
- VII. Arbitration/Mediation

3. CIVIL TRIAL

- I. Opening Statements
- II. Case-in-Chief - (Plaintiff presents evidence)
- III. Defense - (Defendant presents evidence)
- IV. Rebuttal - (Plaintiff may have option to call rebuttal witnesses)
- V. Closing Arguments
- VI. Jury Deliberates - Renders Decision

Current Case Status for Luzenac America

- **5 silicosis cases in Texas.** In 2 cases, records show sales of Luzenac talc and chlorite to facility where plaintiff alleges exposure.
- **1 asbestos/silica/talc case in New York.** Records show sales of Windsor unfloated talc to Bondo (body patch).
- **1 asbestos case in Maryland.** Records show sales of Yellowstone talc to facility where plaintiff alleges exposure.
- **1 asbestos case in California.** Rio Tinto companies named in suit. No record of talc usage or exposure. Plaintiff has died and case is being re-served as a wrongful death case.

Specific Litigation Issues & Problems

- **Asbestos exposure claims.** Continue to be filed. Jury awards continue to overwhelmingly favor Plaintiffs. Last year, seven Tyler Pipe employees awarded \$10 million. Luzenac America was a defendant in original pleadings.
- **Crystalline silica claims.** Gaining in popularity – becoming the next generation “toxic tort industry” for legal community.
- **Luzenac America corporate history.** Complicates the defense and accountability of claims:
 - a. 1988 – Cyprus purchases assets of the Vermont Talc company
 - b. 1989 – Cyprus purchases stock of Windsor Minerals – Indemnity provisions in Sales Agreement
 - c. 1992 – Rio Tinto purchases the stock of Cyprus Talc Company. Sales agreement requires Luzenac to assume responsibility in 1993 for all product liability claims on Cyprus sales (pre-1992)
 - d. 1997 – Cyprus acquires Amax Gold
 - e. 2000 – Phelps Dodge acquires Cyprus/Amax
- **Multiple ownership changes.** Site closures, personnel changes, etc., have made record and document discoveries extremely difficult. Pre-1992 Cyprus records still under the legal “privileged” umbrella of Cyprus counsel. Fewer and fewer company “historians” available to provide court permitted testimony (in lieu of documentation).
- **“Deep Pockets”.** Traceability to Rio Tinto will put/keep Luzenac on many “radar screens”. Larger settlement demands will be put upon Luzenac for dismissal.
- **R. T. Vanderbilt.** Publicity on N.Y. State talc/tremolite issues continues to reinforce the talc/asbestos association e.g., the “2000 Crayon controversy – Seattle Post Exposé”.
- **NTP Carcinogenic Listing.** Listing of “talc not containing asbestos fibers” could be potentially devastating from a product liability perspective. [*Plaintiffs attorney: “So Mr. Zazenski, please tell the Court when Luzenac first learned that talc was possibly associated with ovarian cancer?” “When did you first start warning consumers that this association was possible and under study”. “Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the women and children in our society?” Etc. etc. etc.*]

Exhibit 128

Exhibit 128, video of Alex Gorsky, can be accessed at:

<https://lanierlawfirm.sharefile.com/d-s8ae050614a248fb8>

Exhibit 129

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

IN RE:

FOLEY V. AVON PRODUCTS, INC. ET AL.	MID-L-3095-18 AS
FRACE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-600-18 AS
GATMAITAN V. IMERYS TALC AMERICA, ET AL.	MID-L-4252-18 AS
GRABOWSKI V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-6805-16 AS
GREENE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-2456-18 AS
GRIFFIN V. CYPRUS AMAX MINERALS COMPANY, ET AL.	MID-L-4826-18 AS
HODJERA V. BORGWARNER MORSE TEC, LLC, ET AL.	MID-L-5368-17 AS
MCNEILL-GEORGE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-7049-16 AS
SELVAGGIO V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-598-18 AS
WENDOWSKI V. IMERYS TALC AMERICA, INC., ET AL.	MID-L-6635-17 AS

VIDEOTAPE DEPOSITION OF SUSAN NICHOLSON, MD
DAY 2

Transcript of the deposition of the witness,
called for Oral Examination in the above-captioned
matter, said deposition being taken pursuant to
Superior Court Rules of Practice and Procedure by and
before MARC BRODY, a Notary Public and Certified Court
Reporter of the State of New Jersey, at the MIDDLESEX
COUNTY COURTHOUSE, 56 Paterson Street, New Brunswick,
New Jersey, on Wednesday, March 6, 2019, commencing at
approximately 10:00 in the forenoon.

BRODY DEPOSITION SERVICES
235 East Broad Street, Suite 1
Westfield, New Jersey 07090

Phone: 908-789-2000 Fax: 908-789-2007

Brody Deposition Services

Page 204	Page 206
<p>1 APPEARANCES:</p> <p>2</p> <p>3 COHEN, PLACITELLA & ROTH, P.C.</p> <p>4 127 Maple Avenue</p> <p>5 Red Bank, New Jersey 07701</p> <p>6 732-747-9003</p> <p>7 BY: CHRISTOPHER PLACITELLA, ESQ.</p> <p>8 AND: DENNIS GEIER, ESQ.</p> <p>9 Attorneys for Plaintiff</p> <p>10</p> <p>11 HAWKINS PARNELL & YOUNG, LLP</p> <p>12 600 Lexington Avenue, 8th floor</p> <p>13 New York, New York 10022</p> <p>14 646-589-7678</p> <p>15 BY: MANUEL A. GUEVARA, ESQ.</p> <p>16 Attorneys for Defendant, Revlon</p> <p>17</p> <p>18 McGIVNEY, KLUGER & COOK, P.C.</p> <p>19 18 Columbia Turnpike, 3rd floor</p> <p>20 Florham Park, New Jersey 07932</p> <p>21 973-822-1110</p> <p>22 BY: ELIZABETH BARNA, ESQ.</p> <p>23 Attorneys for Defendant, Whittaker, Clark &</p> <p>24 Daniels</p> <p>25</p> <p>18 BLANK ROME, LLP</p> <p>19 One Logan Square</p> <p>20 Philadelphia, Pennsylvania 19103</p> <p>21 215-569-5397</p> <p>22 BY: JAMES T. SMITH, ESQ.</p> <p>23 Attorneys for Defendant, Johnson & Johnson</p> <p>24</p> <p>25</p>	<p>1 INDEX</p> <p>2 WITNESS PAGE</p> <p>3 SUSAN NICHOLSON, MD</p> <p>4 Continued direct by Mr. Placitella 207</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11 ALL EXHIBITS/DOCUMENTS ARE LISTED ON PAGES 356-357</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 205	Page 207
<p>1 APPEARANCES (Cont'd):</p> <p>2</p> <p>3 O'TOOLE, FERNANDEZ, WEINER & VAN LIEU</p> <p>4 14 Village Park Road</p> <p>5 Cedar Grove, New Jersey 07009</p> <p>6 973-239-5700</p> <p>7 BY: GARY VAN LIEU, ESQ.</p> <p>8 Attorneys for Defendant, Colgate-Palmolive</p> <p>9</p> <p>10 McCARTER & ENGLISH, LLP</p> <p>11 Four Gateway Center</p> <p>12 100 Mulberry Street</p> <p>13 Newark, New Jersey 07102</p> <p>14 973-622-4444</p> <p>15 BY: JOHN C. GARDE, ESQ.</p> <p>16 Attorneys for Defendant, Johnson & Johnson</p> <p>17</p> <p>18 ALSO PRESENT:</p> <p>19 Carolyn McNelis, Paralegal, Cohen Placitella & Roth, PC</p> <p>20 Vincent Maggiano, Videographer, Dynamic Evidence</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 THE VIDEOGRAPHER: The time is 10:08 a.m.</p> <p>2 We are now on the video record. Today's date is</p> <p>3 March 6, 2019. This is the videotaped deposition of</p> <p>4 Susan Nicholson. Counsel will be noted in the</p> <p>5 stenographic record. May the court reporter swear</p> <p>6 in the witness and then you may proceed.</p> <p>7</p> <p>8 S U S A N N I C H O L S O N, MD, sworn:</p> <p>9</p> <p>10 CONTINUED DIRECT EXAMINATION BY MR. PLACITELLA:</p> <p>11</p> <p>12 Q Good morning, Dr. Nicholson, how are you?</p> <p>13 A Good morning. Thank you.</p> <p>14 Q As you know that after your last</p> <p>15 deposition we had a conference with the court?</p> <p>16 A Yes.</p> <p>17 Q And it was pointed out to me by the court</p> <p>18 that at certain points in the deposition I could</p> <p>19 have been a little bit more polite to you, and if I</p> <p>20 was impolite in any way, I apologize.</p> <p>21 A Apology accepted.</p> <p>22 Q The court also indicated that there were</p> <p>23 times when maybe you could have been a little bit</p> <p>24 more responsive to my questions. So I told the</p> <p>25 court we would try to work together to try to get</p>

Page 208	Page 210
<p>1 this done. Can we agree?</p> <p>2 A Yes.</p> <p>3 Q We are here in the courthouse now having</p> <p>4 the deposition taken in the courtroom of the</p> <p>5 Honorable Ana Viscomi, and the court will be</p> <p>6 available should we have any issues that we need to</p> <p>7 deal with. Do you understand that?</p> <p>8 A Yes.</p> <p>9 Q Now, since the last time we were together,</p> <p>10 did you review any additional materials?</p> <p>11 A No.</p> <p>12 Q Did you speak to any fact witnesses?</p> <p>13 A No.</p> <p>14 Q Did you discuss the substance of your</p> <p>15 prior testimony with counsel?</p> <p>16 A No.</p> <p>17 Q Has anything happened since the last time</p> <p>18 we were together and today that would cause you to</p> <p>19 change any part of your testimony?</p> <p>20 A No.</p> <p>21 Q Did you spend any additional time between</p> <p>22 the last deposition and today in preparing for your</p> <p>23 deposition?</p> <p>24 A I just looked over the same documents</p> <p>25 again briefly.</p>	<p>1 had occurred.</p> <p>2 Q Were any of these notes based upon any</p> <p>3 conversations with anyone?</p> <p>4 A The attorneys and I did review these notes</p> <p>5 together, but these notes are my notes to guide my</p> <p>6 recollection of the events that occurred.</p> <p>7 Q The notes were based solely on a review of</p> <p>8 documents that were supplied to you. Is that fair?</p> <p>9 A No. There was mention of the Reuters</p> <p>10 articles, which was an article I had read and</p> <p>11 conversations with individuals that we had mentioned</p> <p>12 previously, some notes related to that.</p> <p>13 Q I'm assuming that Prosecco had nothing to</p> <p>14 do with this particular deposition, other than you</p> <p>15 probably thought you needed a drink before you got</p> <p>16 in here?</p> <p>17 A No. I was asked to stop on the way home</p> <p>18 and made the note.</p> <p>19 Q Stop for Prosecco, and I've had witnesses</p> <p>20 tell me I'm challenging, but usually not that they have</p> <p>21 to drink before they come to the deposition.</p> <p>22 A Certainly not.</p> <p>23 Q Let's just walk through your notes so I</p> <p>24 have a sense of what is in here. I won't spend very</p> <p>25 long on it.</p>
Page 209	Page 211
<p>1 Q In your preparing to begin the deposition,</p> <p>2 how much time did you spend, approximately, doing</p> <p>3 that?</p> <p>4 A Probably eight hours.</p> <p>5 Q So like one full day?</p> <p>6 A Well, spread across many days, but eight</p> <p>7 hours, I would say.</p> <p>8 Q You currently are an employee at Johnson</p> <p>9 and Johnson, right?</p> <p>10 A Yes, I am.</p> <p>11 Q And your title again is?</p> <p>12 A Vice-President Women's Health.</p> <p>13</p> <p>14 (PER COUNSEL AGREEMENT, THIS IS THE</p> <p>15 START OF CONFIDENTIAL PORTION BOUND UNDER</p> <p>16 SEPARATE TRANSCRIPT.)</p> <p>17</p> <p>18 Q Last time we marked as P-2 your notes. Do</p> <p>19 you have copies of your notes with you?</p> <p>20 A Yes.</p> <p>21 Q What were the circumstances under which</p> <p>22 you wrote these notes?</p> <p>23 A In reviewing the binders of documents that</p> <p>24 had been provided, I took some notes to create</p> <p>25 context over time for a number of the events that</p>	<p>1 The first thing you say is 1960s, and</p> <p>2 I'll put them under the Elmo so we are all on the</p> <p>3 same page. You say 1960s gras. Read it and tell me</p> <p>4 what you mean by that?</p> <p>5 A In the 1960s talc was reviewed in May,</p> <p>6 gras, generally regarded for safe and use in food</p> <p>7 products.</p> <p>8 Q You have here John Bailey, 1968 joined.</p> <p>9 What does that mean?</p> <p>10 A Tab A of, I don't know which binder, the</p> <p>11 large binder with all the tabs. I don't know what</p> <p>12 number it is. Tab A has an expert report from Dr.</p> <p>13 John Bailey from the FDA and PCPC.</p> <p>14 He joined the FDA in 1968 and then he</p> <p>15 wrote or provided this expert report from his</p> <p>16 experience starting with the FDA to temporary times.</p> <p>17 Q This expert report was is not a Johnson</p> <p>18 and Johnson document, correct?</p> <p>19 A No.</p> <p>20 Q Is it an expert report he actually</p> <p>21 prepared for another defendant in a talc case?</p> <p>22 A I don't know the source of this. I do</p> <p>23 know that John Bailey wrote it as an expert report</p> <p>24 related to the topic of talc safety.</p> <p>25 Q So how did you get it?</p>

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<p>1 A The attorneys gave it to me as part of the 2 file we have related to the take. 3 Q Is he an expert that you hired to assist 4 you in these litigations? 5 A I'm not aware that we have hired him and I 6 wouldn't necessarily know the answer to that 7 question. 8 Q The next thing you have here is 1970s. 9 Could you read what you wrote here and tell me why 10 you wrote it down? 11 A So 1971, the head of the EPA had a 12 symposium related to asbestos in talc and a number 13 of individuals were invited to that. That led to 14 Dr. Lewin's testing of a number of cosmetic talc 15 samples and that eventually led to the formation of 16 the J41 standard. 17 Q Then you have here 1980s. What is that? 18 A In 1984 the first citizen petition was 19 filed. That was denied in 1986. 20 Q Then you have some notes under that, see 21 figure 2.1 page 5, food additives binder. What does 22 that mean? 23 A That means in the binder, the smaller 24 binder, I can't see over there on the desk, but in 25 the smaller binder there's a 1986 response to the</p>	<p>1 asbestos, and I'm assuming that means ovarian 2 cancer? 3 A Yes. 4 Q Why did you write that down? 5 A I would have to look at the citizen 6 petition. I believe both of those topics were 7 raised in that citizen petition. 8 Q And then 1995, you have notes for 1995. 9 What is that? 10 A The CTFA Task Force wrote a letter to the 11 FDA related to that citizen petition. 12 Q Then off to the left you have FDA tested, 13 and then you have three things. What is that? 14 A So as we discussed previously, the FDA did 15 testing in 1976 of cosmetic talc and they did 16 another survey in 2009 and 2010. 17 In 1986, as we discussed in detail 18 last time, the FDA did an extensive analysis of 19 inhalation exposure of talc and other related 20 materials that was put into the response to that 21 1984 citizens petition. 22 Q I'll ask you about that later. And 23 underneath that you have 2009, and you have notes 24 under there. What does that mean? 25 A There was a new citizen petition in 2008</p>
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<p>1 citizen petition, and they are on page 5, figure 2 2.2. There's a table that I made notation to make 3 reference to. 4 Q Okay. 5 A I would have to look at that to tell you 6 exactly what is in that figure. 7 Q Then under 1990s, what is that? 8 A The NTP Rat Study. That was a study that 9 was the methods in that were -- I shouldn't say the 10 methods, the conduct of that study was flawed. The 11 machine broke in the midst of doing that study and 12 led to a high stress situation, what's called 13 overload in the animals, and some of those animals 14 did display some pathology. It was the subject of 15 several documents discussions where experts in the 16 field determined that that rat study did not have 17 any relevance to human health. 18 Q Was that something that Johnson and 19 Johnson discussed with the FDA? 20 A That study has been brought up numerous 21 times with the FDA and would have been part of that 22 1994 ISRTP FDA workshop was one that Johnson and 23 Johnson participated in and members of the FDA were 24 present. 25 Q Then you have 1994 citizen petition,</p>	<p>1 that was part of an April 2014 response by the FDA. 2 I was looking at that because the topic for the 3 deposition today was communications between Johnson 4 and Johnson and the FDA. So I made a note that 5 Kathy Wiley, who was the J & J employee, had spoken 6 to the FDA in that time period, or communicated 7 with, I should say. 8 Q You have Stanley Milstein emailed John B. 9 What does that mean? 10 A I would have to go back and look at the 11 documents related to that period of time. Stanley 12 Milstein wrote an email, probably to John Bailey, 13 but I would have to verify that in the documents 14 that were provided. 15 Q Then underneath that you say PCPC handling 16 interaction. Can you read those notes and tell me 17 what they mean? 18 A So the topic for the deposition is 19 communications between FDA and Johnson and Johnson 20 and Johnson and Johnson and FDA. Around that event 21 of the 2009, 2010 testing, communications with the 22 FDA was through our trade association PCPC. So 23 direct communication between Johnson and Johnson and 24 FDA was at a very minimum and that's why I made note 25 of Kathy Wiley above that.</p>

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<p>1 Q And who is Kathy Wiley?</p> <p>2 A I don't know her exact role. She's long</p> <p>3 since left the company.</p> <p>4 Q When you say the company, do you mean</p> <p>5 Johnson and Johnson?</p> <p>6 A Yes.</p> <p>7 Q Then on the next page, I guess the flip</p> <p>8 side, you have some notes about December 2009. What</p> <p>9 is that?</p> <p>10 A Again, the question was if Johnson and</p> <p>11 Johnson communicated with the FDA, and I found a</p> <p>12 document that showed that John Lemmo, a Johnson and</p> <p>13 Johnson employee, attended a meeting with FDA in</p> <p>14 December 2009.</p> <p>15 Q What is that underneath?</p> <p>16 A 2014, the FDA denied citizen petition.</p> <p>17 Q Then you have a single line and you have</p> <p>18 Reuter's article lays out the theme. What did you</p> <p>19 mean by theme, by the way?</p> <p>20 A So as we discussed previously, there was a</p> <p>21 recent article published by Reuters in late 2018</p> <p>22 that took some of the facts that had been discussed</p> <p>23 related to talc safety and put them out of context,</p> <p>24 which made them difficult to understand the</p> <p>25 implications of. So this section of my notes really</p>	<p>1 information.</p> <p>2 Q You say, for example, we are not playing</p> <p>3 games with language, and then you say go to McCrone</p> <p>4 letters. Is that something you somehow relied upon</p> <p>5 to prove your point?</p> <p>6 A It is not proving a point and provided in</p> <p>7 the binders are two letters. One in the '70s and</p> <p>8 one in the late '80s written by McCrone, who did the</p> <p>9 testing for our production material of talc and</p> <p>10 other sort of evaluations of talc for asbestos.</p> <p>11 And, for instance, I believe it was 1986, McCrone</p> <p>12 said in the previous fifteen years they never seen</p> <p>13 asbestos in production material of talc.</p> <p>14 So whatever discussions had taken</p> <p>15 place in that 15 years prior, the McCrone testing</p> <p>16 letter basically says there's no asbestos in Johnson</p> <p>17 and Johnson talc.</p> <p>18 Q And that testing letter you are talking</p> <p>19 about, that doesn't have any testing results itself</p> <p>20 in it, does it?</p> <p>21 A No. It is talking about the body of</p> <p>22 testing that had been done for the previous 15</p> <p>23 years.</p> <p>24 Q We will do some of that later.</p> <p>25 Here you have under the similar thing,</p>
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<p>1 takes some of those facts that could be taken out of</p> <p>2 context and puts them in the historical context of</p> <p>3 what was happening at that time.</p> <p>4 Q What did you mean when you say lays out</p> <p>5 the theme?</p> <p>6 A For instance, this first note says we are</p> <p>7 not playing games with language. There was a lot of</p> <p>8 confusion about asbestos and the misclassification</p> <p>9 of asbestos historically. And when people use the</p> <p>10 term tremolite, they are -- It is sometimes put in a</p> <p>11 way where it implies that tremolite is asbestos and</p> <p>12 that is not true. So the precision of language and</p> <p>13 implication is critical to understanding the facts</p> <p>14 and events related to talc safety.</p> <p>15 Q So it says Reuters article, later pivot</p> <p>16 back to. Why did you write pivot?</p> <p>17 A Meaning, if an individual fact, for</p> <p>18 instance, from some period between 1971 and 1976, if</p> <p>19 an individual communication is taken out, that</p> <p>20 almost certainly is misleading because at that time</p> <p>21 scientists, the FDA, really no one had any agreement</p> <p>22 on what the appropriate testing was for asbestos.</p> <p>23 So taking that out of -- pivot back</p> <p>24 to means provide the context for those individual</p> <p>25 points to be sure that there's no misleading</p>	<p>1 no documentation that a validated positive test for</p> <p>2 asbestos, then that material was used. Can you</p> <p>3 tell me what all that is?</p> <p>4 A In essence, we have standards, release</p> <p>5 specifications, certificates of analysis, for</p> <p>6 instance, that are related to how we manufacture and</p> <p>7 test our products. And any lot that is released to</p> <p>8 make production material needs to pass those</p> <p>9 standards, and one of those standards is no asbestos</p> <p>10 detected.</p> <p>11 Q And that is something you have personal</p> <p>12 knowledge of or information you gleaned from looking</p> <p>13 at documents?</p> <p>14 A I'm sorry, I don't really understand the</p> <p>15 question. There's two things there.</p> <p>16 Q Was it part of your job to do this or is</p> <p>17 this something you learned in preparation for being</p> <p>18 a witness?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A I don't mean to be evasive. I'm trying to</p> <p>21 understand the question. In my prior role as</p> <p>22 Vice-President Safety Surveillance and Risk</p> <p>23 Management for the Consumer Products, it was my job</p> <p>24 to oversee the safety of all products that we make</p> <p>25 in Consumers.</p>

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<p>1 So my team, and myself, that was our 2 primary job, and one of those jobs is to ensure that 3 the specifications relevant to medical implications 4 of the use of our products are appropriate. 5 So, yes, understanding those 6 standards was part of my job. I have looked at 7 those standards, read them, discussed them with our 8 quality engineers, reviewed many, many test results 9 from over the years, so I have first hand knowledge 10 those standards are appropriate and implemented 11 100 percent of the time. 12 Q We will get to that. Then you say 13 underneath that, and I assume that means the 14 standards were set such that exposures less than 15 environmental exposures, then you have a bunch of 16 language. Could you explain that? 17 A Yes. So the standards were set between 18 that period of 1971 and 1976, and that was a 19 discussion with many experts in the field and again, 20 it is well described in that 1986 response to the 21 citizen petition. 22 The standards were set such that any 23 exposure someone might theoretically get with the 24 testing limitations that are set by the J41 standard 25 would be -- I think I have to go back, but certainly</p>	<p>1 Another scientific group got together 2 with the FDA and Dr. Lewin and determined that Dr. 3 Lewin's testing methods were inadequate and he was 4 misreading largely chlorite for chrysotile asbestos, 5 and he later retracted his results publically. And 6 Pooley and McCrone were two of the expert groups who 7 looked at those samples and determined that there 8 were not, in fact, asbestos in them. 9 The FDA retested those samples, found 10 there was not, in fact, asbestos in them, and then I 11 make a note here that there are miners and millers 12 that handled the very talc used that was used in 13 these products, and despite many years of 14 occupational exposure to those materials, there was 15 no evidence there was asbestos-related disease in 16 those miners or millers of cosmetic grade talc. 17 Q Let's go through your notes and we will 18 back and touch on all of these. 19 Next, Boundy study '75, '76. Tell me 20 what's in your notes. 21 A I would have to go back and pull the 22 Boundy study. 23 Q Rachel, no read, Rubin and discuss. What 24 does that mean? 25 A Rubino. This is Rachel Weinstein, who is</p>
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<p>1 less than a lifetime exposure of asbestos just 2 breathing air. 3 So the calculation and the testing 4 methods were set such that there was no chance that 5 the exposure you would get from using talc would 6 come anywhere close to what you would get in normal 7 day-to-day life. 8 Q We will spend some time. I just want to 9 understand your notes. 10 On the next page 3, you say ACP, 11 Langer, Pooley, Lewin. Tell me what all that is. 12 A I don't remember what ACP means, but I do 13 know Dr. Langer from Mount Sinai did testing of talc 14 in the early '70s. He thought he had seen asbestos. 15 Many experts looked at those results 16 and determined that, in fact, he was incorrect, that 17 what he had seen what's called rolled talc and he 18 later retracted saying those were not his results 19 and they were preliminary and in effect, he had made 20 a mistake. 21 Q Okay. 22 A Dr. Lewin, similarly he was hired in the 23 early '70s by the FDA to test cosmetic talc and he 24 tested more than 100 samples and thought that he had 25 seen many samples that contained asbestos.</p>	<p>1 a PhD epidemiologist at Johnson and Johnson. And 2 Rubino is one of the Miner, Miller studies, and I 3 was interested in understanding if there was any 4 critique of the methods that were used, anything 5 perhaps that I should understand more than I did by 6 reading it myself. 7 We did discuss it and my 8 understanding of the results were what I thought 9 they were. The other one was just a random note. 10 Q Email travel dates. What is July 15th, 11 case starts? What does that mean? 12 A I was told there could be a case that they 13 would like me to help prepare for. 14 Q I'm getting there. Talk to me about the 15 notes on the next page that I have here starting 16 with Natasha. Go through your notes for me. 17 A So Natasha is our head of, and I have to 18 look up her last name, is the head of quality for 19 Consumers. She started after I left my Consumer 20 role. She has knowledge of the history of testing 21 of asbestos and I wanted to confirm some of my 22 recollection of our worldwide testing program, and 23 those notes below that are related to the questions 24 that I wanted to get clarification that we have been 25 doing a worldwide testing for asbestos since the</p>

<p style="text-align: right;">Page 224</p> <p>1 year 2000 to present where we pull material off the 2 shelves and test for asbestos.</p> <p>3 Pre 2000 we did -- the redundancy was 4 that not only do J41, but we use electron microscopy 5 sampling and so forth.</p> <p>6 Q Here you have 1938 FDCA. What does that 7 mean?</p> <p>8 A Food and Drug Cosmetic Act was adopted in 9 1938.</p> <p>10 Q And then you have underneath that a 11 Jifsan.UMD.edu. What is that all about?</p> <p>12 A In the fall of this past year the FDA had 13 a meeting that industry did not participate in to 14 discuss current methodologies for asbestos testing 15 in talc.</p> <p>16 Some of the individuals who attended 17 that meeting had acted as experts for Johnson and 18 Johnson, which we disclosed to the FDA. Related to 19 the topic of the deposition, which is communications 20 Johnson and Johnson has with the FDA and FDA has 21 with Johnson and Johnson, we did communicate to them 22 some of those individuals had functioned as experts 23 on this matter for Johnson and Johnson.</p> <p>24 Q And who were those individuals?</p> <p>25 A I would have to check other notes to</p>	<p style="text-align: right;">Page 226</p> <p>1 meeting. I don't know that we supported their 2 travel to that meeting or not. I would have to 3 verify whether or not that's true.</p> <p>4 Q When you took these notes down, where were 5 you and who were you talking to?</p> <p>6 A I don't recall.</p> <p>7 Q But your notes say, as it relates to the 8 November meeting, "paid for the people to go to 9 meeting." Correct? That's what they say?</p> <p>10 A I didn't put them in quotations. That was 11 a note to myself to verify whether or not that was 12 true. I guess I forgot to put a question mark 13 there.</p> <p>14 I don't know whether we did or did 15 not pay for individuals to go to the meeting. But 16 those experts that participated in the meeting were, 17 in fact, people that had worked for Johnson and 18 Johnson as experts on the talc related safety 19 issues.</p> <p>20 Q Did they work for Johnson and Johnson as 21 experts in litigation?</p> <p>22 A They worked for experts. I don't recall 23 the exact names of the experts, so I don't know what 24 capacity they might have worked on. I have not 25 worked directly with any of these experts to my</p>
<p style="text-align: right;">Page 225</p> <p>1 verify. I don't know right off the top of my head.</p> <p>2 Q Then here it says paid for people to go to 3 meeting. What does that mean?</p> <p>4 A I would have to check. I understood we 5 had hired those experts previously and they had 6 worked for Johnson and Johnson. I'm not -- I have 7 not confirmed, in fact, anybody supported the travel 8 of those individuals to the meeting. I would have 9 to double check that.</p> <p>10 Q Why did you write down paid for people to 11 go to meeting?</p> <p>12 A These are my notes. I would call it an 13 aid memoir. Things to stimulate my memory so that I 14 would, as I was looking through documents, be on the 15 lookout for those things. So they are not declared 16 as statements per se, but comments to help stimulate 17 my memory as I look through what amounts to many 18 hundreds and hundreds of pages of documents.</p> <p>19 Q I get that, but you talk about a meeting 20 in November. You say that it was not for industry, 21 but then your notes say that you paid for people to 22 go to the meeting. Why did you write that down?</p> <p>23 A So I did not say that we paid for people 24 to go to the meeting. We have employed as experts 25 some of the individuals that participated in that</p>	<p style="text-align: right;">Page 227</p> <p>1 recollection.</p> <p>2 Q You wrote Mike Fedala worked together. 3 What is all that?</p> <p>4 MR. SMITH: Objection.</p> <p>5 Q I highlighted it. What do notes mean?</p> <p>6 A So we were -- I was talking to a number of 7 individuals and Tim is Tim McCarthy, trying to 8 understand how we learned about the meeting that FDA 9 was calling on November 28th.</p> <p>10 So the topic for the deposition was 11 communications between Johnson and Johnson and the 12 FDA and FDA and Johnson and Johnson. We had met 13 with FDA in June and I was trying to recreate how it 14 is that Johnson and Johnson had gotten 15 communications from the FDA about that meeting.</p> <p>16 So I asked Tim, and apparently there 17 were a number of people sending emails, and that's 18 how this meeting came about. Someone named Mike 19 Fedala called Tim who used to work with Stanley 20 Milstein, who is now with the FDA, who sent an 21 email to Tim.</p> <p>22 Anyway, that's related to how we knew 23 that the FDA was interested in having a discussion.</p> <p>24 Q Underneath it you have a star and it says. 25 "How were the three experts selected?" What did</p>

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<p>1 you mean by that?</p> <p>2 A So in that meeting in June, the FDA asked</p> <p>3 us if we had recommendations of experts in asbestos</p> <p>4 testing. They specifically said they do not</p> <p>5 internally have that expertise, and if we had anyone</p> <p>6 that should be considered as possible participants,</p> <p>7 that we should submit those names. And apparently</p> <p>8 we gave three expert name recommendations, and I was</p> <p>9 trying to figure out how we selected those</p> <p>10 particular names.</p> <p>11 Q Was one of them Ann Wiley?</p> <p>12 A Not that I recall, but again, I don't</p> <p>13 remember the exact names of the experts.</p> <p>14 Q Then you say Lynne --</p> <p>15 A This is Lynne Szczepaniak.</p> <p>16 Q Then you have "no." What does that mean?</p> <p>17 A I was trying to get -- we mentioned before</p> <p>18 that one of the people I reached out to was Lynne</p> <p>19 Szczepaniak, who was our Global Head of Regulatory</p> <p>20 Affairs for Consumer to ask her if she knew where</p> <p>21 the three expert names came from and how we picked</p> <p>22 them.</p> <p>23 Q What did you find it?</p> <p>24 A She didn't know. I asked her if, also</p> <p>25 related to communications to and from the FDA, if</p>	<p>1 page 1. I spoke to Don Hicks and John Hopkins about</p> <p>2 these topics. Then there was a note about something</p> <p>3 else I was working on at the same time.</p> <p>4 Q Did you speak to Hicks or Hopkins in</p> <p>5 reference to this deposition?</p> <p>6 A Not in reference to this deposition.</p> <p>7 Q To prior testimony you gave?</p> <p>8 A Don related to -- Don and I worked</p> <p>9 together, so we have talked many times about</p> <p>10 asbestos testing and I made note that either one</p> <p>11 these two gentlemen would have additional</p> <p>12 information related to asbestos testing if needed,</p> <p>13 but I didn't feel after reviewing the documents I</p> <p>14 needed to discuss with them further.</p> <p>15 Q The last time we were together one of the</p> <p>16 things we reviewed were what representations Johnson</p> <p>17 and Johnson made to the FDA concerning the asbestos</p> <p>18 content of Johnson and Johnson's cosmetic talc. Do</p> <p>19 you recall that?</p> <p>20 A Yes.</p> <p>21 Q And I believe you are testified that the</p> <p>22 issue of whether there was any evidence of asbestos</p> <p>23 in Johnson and Johnson cosmetic talc was raised</p> <p>24 repeatedly over the years by the FDA, correct?</p> <p>25 MR. SMITH: Objection.</p>
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<p>1 any FDA had reached out after the Reuters article</p> <p>2 was published and she said no.</p> <p>3 Q Then the next thing you have is bold</p> <p>4 initiative. What does that mean?</p> <p>5 A Unrelated to this topic, but it has to do</p> <p>6 with looking at the talc safety issue and putting</p> <p>7 together a compendium of scientific information</p> <p>8 related to that. That was a topic that Lynne and I</p> <p>9 also discussed.</p> <p>10 Q And you have the word briefing book. What</p> <p>11 is the briefing book?</p> <p>12 A There's no briefing book. This was a</p> <p>13 discussion around putting a compendium of scientific</p> <p>14 information that would be similar to a briefing book</p> <p>15 they might prepare for FDA, for instance.</p> <p>16 Q And was that prepared?</p> <p>17 A No, we have not prepared that.</p> <p>18 Q The last page, page 5, can you just go</p> <p>19 through that in order and tell me what all this</p> <p>20 means. It starts with '60s, Bailey.</p> <p>21 A So this is redundant. In the '60s, Bailey</p> <p>22 had some summary in his expert report that I made</p> <p>23 reference to earlier.</p> <p>24 There are a number of documents about</p> <p>25 Langer and it points to tab B of this large binder,</p>	<p>1 A Could you please repeat the question?</p> <p>2 Q Sure. You testified last time that the</p> <p>3 issue of whether there was any evidence in asbestos</p> <p>4 in Johnson and Johnson talc was raised repeatedly by</p> <p>5 the FDA to Johnson and Johnson over the years,</p> <p>6 correct?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A Yes, but it was more around testing, not</p> <p>9 the presence of asbestos, to clarify your question.</p> <p>10 Q I'm going to go to your testimony last</p> <p>11 time at page 87, line 10. I'm going to play for you</p> <p>12 your testimony.</p> <p>13</p> <p>14 (Videotape played from previous</p> <p>15 testimony)</p> <p>16</p> <p>17 Q Now, am I correct whether there was</p> <p>18 asbestos in the Johnson and Johnson talc products</p> <p>19 was raised repeatedly by the FDA beginning in the</p> <p>20 early '70s?</p> <p>21 A It was raised. I don't know what that</p> <p>22 means.</p> <p>23 Q The issue was, the question came up over</p> <p>24 and over again, beginning in the 1970s, and was</p> <p>25 posed to Johnson and Johnson, whether any Johnson</p>

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<p>1 and Johnson talc product contained asbestos. Can we 2 agree with that? 3 MR. SMITH: Objection. 4 A That's correct and Johnson and Johnson 5 talc never contained asbestos. 6 BY MR. PLACITELLA: 7 Q Do you recall giving that testimony? 8 A I do, yes, and -- 9 Q That's my question 10 Do you recall giving 11 that testimony? 12 A Yes. 13 Q Do you recall telling me last time that 14 the answer always was that there was never any 15 evidence of any amount of asbestos in Johnson and 16 Johnson talc? 17 A I would have to understand the context of 18 that answer. 19 Q I'll play your testimony from the last 20 time again. 21 (Videotape played from previous 22 testimony) 23 Q The answer by Johnson and Johnson was 24 always the same, correct? 25 That is, there is no evidence of</p>	<p>1 A I hear what you are saying, yes. 2 Q Ultimately we will let the experts and the 3 court and the jury determine whether what you 4 disclosed or didn't disclose was significant or not. 5 Can we agree? 6 MR. SMITH: Objection. 7 A That's fine, yes. 8 Q I want to approach you for a second with 9 volume 1. I'm not being rude here, and as I recall 10 volume 1, which is marked P-3, it is a compendium of 11 everything you ever sent to the FDA, concerning 12 testing of Johnson and Johnson cosmetic talc for 13 asbestos. Correct? 14 A Not exactly, no. 15 Q What is volume one? 16 A Volume 1 is a representative of the 17 communications that we had back and forth with the 18 FDA. Substantive documents are here and multiple 19 copies of the same topic are not necessarily 20 included. 21 If you pull out tab C, which I've 22 done and put over here, there were a number of 23 documents from the early '70s that we could not 24 locate, and so they are not necessarily included in 25 that binder.</p>
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<p>1 any asbestos of any -- strike that. 2 The answer provided by Johnson and 3 Johnson was always the same. There is no evidence 4 of any amount of any asbestos in any of Johnson and 5 Johnson cosmetic product, correct? 6 A There was no asbestos in Johnson and 7 Johnson products, correct. 8 Q Do you recall giving that testimony? 9 A Yes. 10 Q Now, today I want to spend some time 11 reviewing exactly what information was provided by 12 Johnson and Johnson to the FDA to support those 13 representations. 14 We are on the same page? 15 A Yes. 16 Q And I also want to explore what 17 information was in the possession of Johnson and 18 Johnson that was not provided to the FDA. 19 Are you with me? 20 A I don't know what you are referring to, 21 but I hear what you are saying. 22 Q On the subject of asbestos testing in 23 Johnson and Johnson talc. 24 We are going to go through 25 that. Are you with me?</p>	<p>1 Q Everything you could find in terms of 2 communications with the FDA written is in volume 1, 3 P-3, correct? 4 A Not exactly. Anything of substance is 5 here that I'm aware of. 6 Q And you have a copy, a duplicate of this 7 in front of you? 8 A Yes, I do. 9 Q So what I want to do now is I want to make 10 sure we are all on the same sheet of music, okay, in 11 terms of what is in this book and what was provided 12 to the FDA. Okay? 13 A Yes. 14 Q Are you with me? So what I would like you 15 to do is go through the binder with me and let's 16 just make sure we have a clean record of everything 17 in this binder that was provided to the FDA on the 18 subject of whether any test -- scratch that. Let me 19 do it again. 20 Let's go through the binder and make 21 sure we are in agreement on the same sheet of music 22 as to what testing results were provided to the FDA 23 by Johnson and Johnson concerning asbestos in 24 Johnson and Johnson talc products. Are you with me? 25 A Yes.</p>

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<p>1 Q Why don't you start and I'll mark my book 2 at the same time. Let's walk through the book. 3 A I'm sorry, what information do you want? 4 Q I want to go through and mark in the book 5 on the record what testing results you transmitted 6 to the FDA. You, Johnson and Johnson, for asbestos 7 in cosmetic talc that was sold by Johnson and 8 Johnson. Okay? 9 A Okay. In tab 1 there's a memo here making 10 note of three different reports on talcum powder 11 that was transmitted to the FDA. 12 Q The memo you are talking about is July 8, 13 1971? 14 A Correct. 15 Q That's a correspondence from Johnson and 16 Johnson to the FDA, correct? 17 A Correct. 18 Q But those aren't the results themselves. 19 The results are attached, correct? 20 A Correct. 21 Q So what are the results? Let's just talk 22 about the results so we make sure. 23 A Well, the particle size distribution does 24 not have to do with asbestos, so we can go past 25 there one. Number 2 is x-ray analysis of 344L,</p>	<p>1 A Thank you. This is x-ray analysis, which 2 has a limit of detection. 3 Q I'm going to go through each one with you 4 I promise and you can talk about it. All I want to 5 do is identify and then we will go back through each 6 one. Okay? 7 A Okay. 8 Q I want to make sure we are on the same 9 sheet of music. Okay? 10 A Okay. I'm following. 11 Q The next test I can find was under 9, tab 12 9A. Let me know if you see one in between. There's 13 a reference in July 9, 1971 to the FDA meeting 14 July 8th. Dr. had shared electron microscopy 15 photographs at a meeting. 16 Q But there are no test results in that, is 17 there? Raw results from an expert? 18 A Well, I believe that electron micrograph 19 would be a test result. If you can clarify the 20 definition, then maybe we can. 21 Q I'm looking for the reports that you gave 22 to the FDA concerning the test results related to 23 asbestos in talc. 24 A So you want only reports? 25 Q Yes, the solid reports.</p>
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<p>1 which is a representative sample from Vermont. 2 Q Okay. Where is that? 3 A I'm looking. 4 Q Is that the Dartmouth report? 5 A The third one is the Dartmouth report. 6 Q That's June 28, 1971? 7 A That's correct. 8 Q Okay. 9 A And that's attached. None of the results 10 here mention, that I can see just on a glance, the 11 presence or absence of asbestos, but it talks about 12 a number of other substances that were looked at, 13 for instance, chlorite and such. 14 Q Well, actually, if you go to page 5 of the 15 report, and we will back to it, it does talk about 16 results on number 10, doesn't it? 17 A You are correct. No amphiboles or 18 asbestos were observed. Thank you. 19 Q Then am I correct the next set of tests is 20 a July 7, 1971, from the Colorado School of Mines? 21 A That is correct. I'm looking for that 22 report. 23 Q I think it is the very next page. 24 A Thank you. 25 Q I'll pull it up here on the screen.</p>	<p>1 A Okay. There are meetings minutes that 2 refer to a number of tests. I'm looking at 9, as 3 you point out, and there's a reference to a series 4 of reports. There's the Pooley report, the McCrone 5 report, a letter from the Colorado School of Mines, 6 a report on particle size, another report from Dr. 7 Pooley and some reports from the McCrone folks. 8 Q Okay. Let's identify them. Under 9A you 9 have the Pooley report? 10 A Yes. 11 Q I'll put a tab there. The next report I 12 see is 9D from McCrone. Is that correct? 13 A There are other reports related 14 specifically to asbestos testing, I believe is your 15 question. 16 Q Correct. 17 A There is a report in tab C that makes 18 reference to numerous different types of evaluations 19 of talc product. 20 Q Are there any results of the asbestos 21 testing in 9C, because I didn't see them? Actually, 22 you are correct. I think this is repeated. Okay. 23 So 9C. 24 A In conclusion, it makes reference to 25 testing for asbestos.</p>

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<p>1 Q I got it. Where it says samples 1 through 2 10, right? 3 A Correct. 4 Q We will come back to that? 5 A The next report is from McCrone on 344L 6 sample. 7 Q That's dated August 19, 1971? 8 A Yes. 9 Q I have it up on the screen. To make sure 10 we are all on the same page. 11 A Yes. 12 Q What is the next one? 13 A This is not results, but in tab E is the 14 methods used by McCrone. 15 Q They don't contain any results? 16 A Correct. 1971 to 1976, the methods were a 17 primary focus on testing. 18 Q I promise I'll give you all the time you 19 need to talk about those things. 20 The next one I have is tab 27. Mine 21 says 27A, Sperry-Rand. 22 A Tab 14 makes mention of internal J & J 23 testing of the same samples or samples from the same 24 lots that Professor Lewin had tested. There's a 25 report, but there's a communication to the FDA, our</p>	<p>1 Q But those actual tests results are here, 2 right, in this book, the McCrone results? 3 A I would have to track to make sure it is 4 the exact sample they are making reference to. 5 Q There's no test results on page 2, it is 6 just a summary statement, correct? 7 A That's the test results were reported to 8 the FDA. That's what it says. I thought that's 9 what you were asking. 10 Q I want to just highlight it. So you are 11 talking about now tab 16? 12 A Tab 16. 13 Q On page 2? 14 A Yes. Second paragraph. Dr. Stewart, from 15 McCrone Associates, reviewed his findings on the 16 Lewin Shower to Shower sample. He stated all 17 samples were subject to electron microscopy. No 18 chrysotile present at the end of that paragraph. 19 MR. SMITH: I want to place my 20 objection to highlighting on the originals. I 21 object to it. I don't think you should do it. 22 MR. PLACITELLA: I'm doing it so we'll 23 have it. She has got a copy. 24 MR. SMITH: My copy. 25 MR. PLACITELLA: Okay.</p>
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<p>1 test showed no asbestos in samples. 2 Q I want to make sure I got that. That's 3 tab 25C? 4 A This is tab 14 I'm looking at, August 8, 5 1972. 6 Q My fault. Sorry. August 8, 1972? 7 A Correct. 8 Q Make sure we have a picture of that. 9 That's it, right? 10 A Yes. 11 Q Go ahead. Keep going. 12 A There's another mention in the document in 13 15, which is a memorandum of a meeting by the FDA 14 That's on page 3. It is referencing to the same 15 testing results. 16 Q But the results are on tab 14, correct? 17 A The same information is conveyed in both 18 of those documents. 19 Q What is next? 20 A There's reference in tab 16 that McCrone, 21 in addition to the J & J scientists' role, and one 22 other scientist mentioned in those two previous 23 documents on page 2, there's mention of McCrone also 24 testing the Lewin Shower to Shower sample and 25 finding that there was not asbestos in that sample.</p>	<p>1 Q What is the next document? 2 A There's some back and forth in August 3 about additional looks at various samples. 4 Q But no results, no published results, 5 correct? No reports? 6 A No, but communication to the FDA regarding 7 reports. 8 Q I'm going to go through that. All I'm 9 trying to do now is identify the actual reports that 10 were provided. Are we on the same page? 11 A I understand. 12 Q Okay. So what is the next actual physical 13 report that's in this binder you provided? 14 A There's a September memo that makes 15 reference to data shared by Dr. Pooley with the FDA. 16 The actual report is not here, but reference to a 17 communication of test results is made note of. 18 Q What is the actual report, the next actual 19 report that you provided? 20 A I realize you are asking for a physical 21 report. There are multiple communications that 22 reference data that isn't in a specific report, but, 23 forgive me, I'm going page by page to make sure to 24 get what you need. 25 Q Go ahead.</p>

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<p>1 A There's a memo in tab 26, I believe you 2 referenced before, looking at some analyses that 3 were done from McCrone. And there's some scanning 4 electron micrographs included, and I think that 5 might fall under your definition of report. 6 Q Tell me what you are referring to. 7 A Tab 26, memo to Ian Stewart from Walter 8 McCrone. 9 Q I don't see anything on tab 26 itself. 10 I'm sorry. 26. Show me where in tab 26 are you 11 referring to. I have it up on the screen. 12 A Starting on page 3, there are electron 13 micrographs. I think that might meet your 14 definition of a report. 15 Q Okay. And that's identified? 16 A Tab 27, there are multiple reports here on 17 the Italian mine investigation of Shower to Shower 18 included in the tabs following tab 27. 19 Q Let's identify each one, please. 20 A October 17, 1972 to Dr. Schaefer. 21 Q That's the cover letter, correct? 22 A Correct. The reports are listed there. 23 Q So A, tab A is a report from Sperry-Rand? 24 correct, dated September 8, 1972? 25 A Yes.</p>	<p>1 that was delivered to Dr. Schaffner on February 14, 2 1973. I'm looking at Talc Versus Asbestos in Long 3 Term Animal Studies. The report itself it appears 4 was not retrieved. 5 Q Okay. 6 A The next one is -- I don't see the date on 7 the report. The cover letter is dated May 25, 1973. 8 Q Okay. The next report I was able to 9 identify is in tab 36, but you can verify that for 10 me? 11 A That's what I find as well, November 9, 12 1973. 13 Q So there's a cover letter from Johnson and 14 Johnson to Dr. Schaefer and it attaches various 15 reports related to Shower to Shower, correct? 16 A That is correct. 17 Q And the first report is from Martin 18 Buerger, October 7, 1972? 19 A That is correct. 20 Q The next report is from Gordon Brown? 21 A That is correct. 22 Q The next report after that is from McCrone 23 dated June 22, 1973? 24 A That is correct. 25 Q The next report is from Colorado School of</p>
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<p>1 Q Tab B is correspondence, right? Tab C, I 2 have an October 27, 1972 report from Colorado School 3 of Mines. Is that right? 4 A Yes. 5 Q The next report I see is a report from 6 McCrone dated 10-27-72 concerning Johnson's Baby 7 Powder? 8 A That is correct. 9 Q The next report I see is a report from 10 Gordon Brown concerning an x-ray study of Johnson's 11 Baby Powder, correct? 12 A Yes. 13 Q The next report that I see is an October 14 31, 1972 report from Professor Pooley on baby 15 powder. Is that correct? 16 A Yes. The cover letter is dated in 17 November, but the report itself is October 31. 18 Q The next report I see is a November 8, 19 1972 report internally from Johnson and Johnson. Is 20 that fair? 21 A That's what it look looks like, yes. 22 Q And I don't see any other reports until 23 tab 31. Can you verify that? 24 A There's reference a report that I don't 25 see here in tab 30. It makes reference to a report</p>	<p>1 Mines, September 7, 1972, correct? 2 A That is correct. 3 Q The next report is from Dr. Pooley dated 4 September 29, 1972, correct? 5 A That is correct. The next is from Dr. 6 Pollack from Carnegie Mellon. 7 Q I don't see any results in this. It is 8 just a comment on Lewin's report, right? There's no 9 actual testing results in this one? 10 A Hold on. That's one interpretation. This 11 person has looked at those results and given their 12 interpretation. Although it is in a cover letter, 13 it is a report of an interpretation. 14 Q Okay. The next one is an internal report 15 from Johnson and Johnson, September 28, 1972? 16 A That is correct. 17 Q Are there any other reports, test results 18 like this after September 28, 1972? 19 A I'll have to continue to look to verify. 20 There's a report in tab 41. 21 Q Excuse me? 22 A Tab 41. 23 Q Okay. 24 A There's a report on detection at low 25 levels of chrysotile asbestos by differential</p>

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<p>1 thermal analysis. So it is a testing methodology 2 that related to our talc product. 3 Q But no test results. 4 A Do you mean -- what do you mean? 5 Q They looked at the Johnson and Johnson 6 talc, they ran a test and this is what they found. 7 With an actual test result. We found asbestos. We 8 didn't find asbestos. We found tremolite. We 9 didn't find tremolite. That's what I'm talking 10 about. 11 A One minute. I'm looking. This is a 12 methods paper on what the detection limits are. You 13 are right. It doesn't list this talc, this talc and 14 the other talc in the results of the test. 15 Q It didn't test the specific product and 16 say these are the results, it is just talking about 17 methods, correct? 18 A It is a methods paper. That's correct. 19 Q Would this be a good time to take a break 20 and kind of peruse it off the camera to see if 21 there's anything else? 22 A Sure. 23 THE VIDEOGRAPHER: The time is 11:20. 24 We are going off the video record. 25 (Recess taken)</p>	<p>1 asbestos and listed here. 2 Q Hold on. I have tab 50 as a May 16, 3 1975 -- 4 A I'm sorry. 52. 5 Q 52. 6 A This is a letter from George Sandlin, who 7 is chairman of FDA Talc subcommittee, Robert Schaffner 8 at the FDA. On page 2 it makes reference to a 9 number of cosmetic products that were tested for the 10 presence of asbestos. J & J products are included 11 in that. 12 Q The reference to a report by Dr. Pooley, 13 isn't that the earlier report we went over? 14 A I would -- it says all done by Pooley. I 15 would have to go back and double check they were the 16 same exact ones. 17 Q But there's no Pooley report. 18 A Correct. There's no report here, but 19 there's reporting of results to the FDA. 20 Q There's no analysis? 21 A I don't know what that means, analysis. 22 Q It doesn't have -- there's no report from 23 Dr. Pooley. It is somebody relating what they think 24 or believe Dr. Pooley found. There's no report from 25 Dr. Pooley, correct?</p>
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<p>1 2 THE VIDEOGRAPHER: The time is 11:34. 3 We are now back on the video record. Counsel, you 4 may proceed. 5 Q When we left off you were going through 6 the binder to identify any other testing report 7 related to whether or not there was asbestos in 8 Johnson and Johnson talc. Did you find any others? 9 A I did. 10 Q What is the next one you found? 11 A Tab 45. There's a letter to Arnold 12 Schelz at the FDA dated October 4, 1974. 13 In paragraph 2 it makes reference to 14 a report enclosed, which verifies the presence of 15 non fibrous varieties in talc. No chrysotile. The 16 report is not attached, but it makes reference to a 17 report. 18 Q But there's no report? 19 A Right, but you asked me about reports sent 20 to the FDA. 21 Q I just want to make sure we are on the 22 same page. 23 A Yes. Then tab 50. There's a note to Dr. 24 Schaffner at the FDA September 12, 1975, and on page 2 25 of the report of samples that were tested for</p>	<p>1 A These are results being reported from the 2 companies to FDA. So you are right, there isn't a 3 separate report from Dr. Pooley, but the results are 4 reported here. 5 Q We don't know what that refers to, whether 6 it is an earlier report, a new report. We have no 7 idea -- 8 A To your point a second ago, we could go 9 back and look at the Pooley report. I don't know 10 that this is the exact same results. 11 Q We will do that. Keep going. 12 A Tab 52 I believe refers also to those 13 same results, talking about Dr. Pooley and extensive 14 study of samples that offer some clarification of 15 the Pooley results. 16 Q But again, no official report from Dr. 17 Pooley? You do say on the second paragraph, Dr. 18 Pooley's summary report is attached as attachment B. 19 Where is attachment B? 20 A There's attachment A that looks like it is 21 the result in Tab K and there's an attachment B in 22 Tab L. 23 Q So attachment B. But attachment B isn't 24 of any Johnson and Johnson product, correct? It is 25 products from Australia, Brazil, South Korea, China.</p>

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<p>1 There's no specific test in attachment B related to 2 Johnson and Johnson products.</p> <p>3 A In 1975, material was being sourced from 4 Italy and talc origin in Italy, that would refer to 5 the source material for Johnson and Johnson talc.</p> <p>6 Q Where does it say that?</p> <p>7 A I know that to be true.</p> <p>8 Q You were still buying talc from Italy in 9 1975? There's no test results here saying this is a 10 Johnson and Johnson product and this is what we 11 found, correct?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A Correct. You asked about results reported 14 to the FDA. Results reported to the FDA. These are 15 the supporting documents and actual physical, 16 separate report is not included here. It may have 17 existed at some time and we don't have it. I'm 18 doing my very best to give you the information you 19 asked for.</p> <p>20 Q Okay. Keep going.</p> <p>21 A Tab 56 makes reference to testing done by 22 a number of companies. If we cross reference -- 23 I'll have to verify it that -- it may be the same 24 data presented on page 2. It delineates all the 25 reports of talc testing that had been done on</p>	<p>1 page. In tab 56 when it talks about tests of 2 Johnson and Johnson product, there is no report, 3 actual report from a scientist either that worked 4 inside of Johnson and Johnson or outside of Johnson 5 and Johnson for Johnson and Johnson. There's no 6 actual authored reports, correct?</p> <p>7 A That's correct. And for clarity, when we 8 share results of tests with the FDA, sometimes a 9 report is sent, sometimes the results are summarized 10 and communicated to the FDA and if they request the 11 report, we will offer to send the report.</p> <p>12 Sometimes it is sent and sometimes 13 it doesn't sent. That's why reporting of the 14 results would be the results whether there's not an 15 attached report.</p> <p>16 Q Keep going.</p> <p>17 A That's all I could find.</p> <p>18 Q Am I correct then that the last report of 19 any results of testing related to asbestos, 20 concerning Johnson and Johnson talc products, was 21 1976 in your book?</p> <p>22 A So, no, because there are test results 23 from the 2009 and 2010 survey that was done by FDA, 24 but that was not -- those aren't test results from 25 Johnson and Johnson or a contractor to the FDA.</p>
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<p>1 Johnson and Johnson talc.</p> <p>2 Q I think we are not on the same page, which 3 is why I'm going through this. 56 is a May 24, 1976 4 letter from Windsor Minerals to McCrone complaining 5 about asking lawyers for quick answers.</p> <p>6 A I'm looking at tab 56 in my book and it is 7 a March 19, 1976 letter.</p> <p>8 Q Okay.</p> <p>9 A On page 2 there's the cover letter and 10 then a subject memo, asbestos in talc, and then a 11 number of different companies are listed, including 12 Johnson and Johnson, which summarizes reports from 13 the numerous evaluations that have been done.</p> <p>14 Q But no actual report itself from a 15 scientist?</p> <p>16 A There's not a physical, separate report, 17 but it reports results from numerous different 18 studies that have been done.</p> <p>19 Q But there's no report directly authored by 20 a scientist, correct?</p> <p>21 A In this tab the source documentation that 22 you are referring to is not included, but there's a 23 listing of results that have been shared with the 24 FDA.</p> <p>25 Q I want to make sure we are on the same</p>	<p>1 Remember 1976, the J41 standard was 2 put in place, so all of the lots of talc would have 3 been tested by that standard and we would have had 4 to pass that standard to be marketed, so the sharing 5 back and forth of test results would have ceased at 6 that point, unless a question was raised.</p> <p>7 Q Maybe I wasn't articulate in my question. 8 As you sit here today, you have no evidence that 9 Johnson and Johnson ever supplied the FDA with any 10 test results concerning the talc for the presence of 11 asbestos or tremolite after 1976?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q Correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A That is correct. That's not something we 16 would have shared, so I don't have that.</p> <p>17 Q After 1976, the FDA continued to ask 18 Johnson and Johnson whether there was any evidence 19 of asbestos in Johnson and Johnson talc products, 20 correct?</p> <p>21 A Yes. The topic of asbestos in cosmetic 22 talc has come up over the years from time to time.</p> <p>23 Q And even though you were asked after 1976, 24 you never supplied the FDA with any test results 25 related to the Johnson and Johnson talc concerning</p>

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<p>1 asbestos or tremolite after 1976, true?</p> <p>2 A That would be true because the only thing</p> <p>3 we would have had is a certificate of analysis that</p> <p>4 would have been said no asbestos detected.</p> <p>5 Q Are you sure about that?</p> <p>6 A To the best of my knowledge.</p> <p>7 Q Now, let's go back and let's make sure we</p> <p>8 are still on the same sheet of music, based on what</p> <p>9 you testified to so far today.</p> <p>10 What I'm going to do to make sure we</p> <p>11 are in agreement is I'm actually going to create a</p> <p>12 chart of everything you have identified and have you</p> <p>13 tell me whether that chart is correct or not so we</p> <p>14 have it all in one place. You got me?</p> <p>15 A Okay.</p> <p>16 Q Let me start with the first test you</p> <p>17 identified, which is the tab 1A, which is the</p> <p>18 Dartmouth test dated June 28, 1971. Do you see</p> <p>19 that?</p> <p>20 A Yes.</p> <p>21 Q And what they did in the Dartmouth test</p> <p>22 is they used an optical microscope and x-ray</p> <p>23 diffraction, correct?</p> <p>24 A Yes.</p> <p>25 Q And they said the purpose of the study was</p>	<p>1 the test revealed. Do you see that?</p> <p>2 A Yes.</p> <p>3 Q What I put for the first entry was the</p> <p>4 date, Dartmouth Reynolds, Miller, studies of ground</p> <p>5 products, using XRD, PLM and what the test revealed</p> <p>6 there were no amphibole or asbestos impurities were</p> <p>7 observed, correct?</p> <p>8 A Yes.</p> <p>9 Q We are on the same page?</p> <p>10 A Yes.</p> <p>11 MR. SMITH: Counsel, are we going to</p> <p>12 mark this as an exhibit?</p> <p>13 MR. PLACITELLA: I will when I'm done</p> <p>14 with it.</p> <p>15 MR. SMITH: Do you have a copy for</p> <p>16 me?</p> <p>17 MR. PLACITELLA: I'll give you a copy</p> <p>18 as I do it, yes.</p> <p>19 MR. SMITH: I can't have a copy?</p> <p>20 MR. PLACITELLA: I can't give you a</p> <p>21 copy. I'm going to keep adding to it. I'll be</p> <p>22 making copies. When I'm done I'll have it printed</p> <p>23 by the court and I'll give you a copy.</p> <p>24 Q The next test I have here is also in 1A</p> <p>25 and that's on the same next page and this is the</p>
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<p>1 to examine the difference in the talc products that</p> <p>2 were produced by various milling procedures,</p> <p>3 correct?</p> <p>4 A Yes.</p> <p>5 Q And this was done by Dr. Reynolds at</p> <p>6 Dartmouth?</p> <p>7 A On the bottom of the report it would say</p> <p>8 who did it.</p> <p>9 Q He looked at both talc ore and talc</p> <p>10 products, correct?</p> <p>11 A Here it says he looked at x-ray and</p> <p>12 optical studies in bulk samples.</p> <p>13 Q And as it related to asbestos on page 5,</p> <p>14 correct, and in number 5 he says, "No amphibole,</p> <p>15 garnet or asbestos impurities were observed during</p> <p>16 optical studies of the products." Correct?</p> <p>17 A Correct.</p> <p>18 Q I created here, to make sure we have this</p> <p>19 down, is the date of the test -- do you see it? On</p> <p>20 your look on your screen.</p> <p>21 A Yes.</p> <p>22 Q The exhibit number, which is your tab</p> <p>23 number, who did the test, the testing entity, the</p> <p>24 author, the recipient, the purpose, the test method,</p> <p>25 if it was shown, the mine, what was tested and what</p>	<p>1 July 7, 1971 Colorado School of Mines. Do you see</p> <p>2 that?</p> <p>3 A Yes.</p> <p>4 Q It talks about doing an x-ray diffraction</p> <p>5 analysis of the Vermont products. Do you see that?</p> <p>6 A Yes.</p> <p>7 Q And what they found was no</p> <p>8 anthophyllite --hold on for a second. What they did</p> <p>9 is they looked at Vermont talc product 344 L,</p> <p>10 correct?</p> <p>11 A Yes.</p> <p>12 Q And they ran x-ray diffraction and the</p> <p>13 conclusion was they found no anthophyllite and only</p> <p>14 minor amounts, below one percent of tremolite and</p> <p>15 actinolite, correct?</p> <p>16 A Yes.</p> <p>17 Q Can we go back to the chart? I put on the</p> <p>18 chart. Still under tab 1A, Colorado School of</p> <p>19 Mines. The report went to Dr. Ashton, correct?</p> <p>20 They used x-ray diffraction of Vermont talc and we</p> <p>21 should add no anthophyllite and only minor amounts</p> <p>22 (below one percent) of tremolite and actinolite were</p> <p>23 detected. Is that good? We are on the same page?</p> <p>24 A Yes, we are on the same page. The</p> <p>25 tremolite and actinolite should not in any way imply</p>

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<p>1 asbestos, because they didn't classify.</p> <p>2 Q Ma'am, they didn't classify it one way or</p> <p>3 another, and I'm not going there, okay?</p> <p>4 A Okay.</p> <p>5 Q We agree they classify it as asbestos or</p> <p>6 non asbestos?</p> <p>7 A Correct.</p> <p>8 Q The next tab I have, I believe from you,</p> <p>9 from is 9A, and that's a report from Dr. Pooley,</p> <p>10 correct?</p> <p>11 A Yes.</p> <p>12 Q And it talks about a report of</p> <p>13 investigations of talc samples supplied by Johnson</p> <p>14 and Johnson, and then lists laboratory code numbers</p> <p>15 1 through 10, correct?</p> <p>16 A Yes.</p> <p>17 Q And it talks about the purpose, which was</p> <p>18 they did an analysis to establish the presence of</p> <p>19 asbestos fiber of the chrysotile or amphibole types,</p> <p>20 correct?</p> <p>21 A Yes.</p> <p>22 Q They used an electron microscope and x-ray</p> <p>23 diffraction, correct?</p> <p>24 A Yes.</p> <p>25 Q What they sampled, if you look on the</p>	<p>1 Q Windsor 66 Talc, correct?</p> <p>2 A Yes.</p> <p>3 Q And I took the quote directly from the</p> <p>4 report. The samples 1-10 were found to be free from</p> <p>5 chrysotile, with the exception of one small</p> <p>6 chrysotile fibril. I should add in parenthesis,</p> <p>7 can I put in just contamination after that? Would</p> <p>8 that satisfy you?</p> <p>9 A I prefer if you write considered</p> <p>10 background contamination.</p> <p>11 Q What did you want to put in there, Doctor?</p> <p>12 A Considered background contamination.</p> <p>13 Q We added the part about no diffraction</p> <p>14 pattern. Is that fair?</p> <p>15 A Yes.</p> <p>16 Q Let's go to, I think the next one you have</p> <p>17 is 9D. You also flagged 9C, but that's a repeat of</p> <p>18 the earlier -- what we just went through, right? It</p> <p>19 is the same document?</p> <p>20 A Yes.</p> <p>21 Q So now 9D is the report to Johnson &</p> <p>22 Johnson Research Center, Examination of Baby Powder</p> <p>23 for Johnson and Johnson by McCrone dated August 19,</p> <p>24 1971. Do you see that?</p> <p>25 A Yes.</p>
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<p>1 front page, is Windsor 66 talc used in the</p> <p>2 manufacture of Johnson's Baby Powder. Do you see</p> <p>3 that?</p> <p>4 A Yes.</p> <p>5 Q And what they concluded, or Dr. Pooley</p> <p>6 concluded, was the samples, 1 through 10, were found</p> <p>7 to be free of chrysotile asbestos fiber, with the</p> <p>8 exception of one small chrysotile fiber, and then he</p> <p>9 goes on to say that that was probably, in his</p> <p>10 opinion, from background. Is that fair?</p> <p>11 A Not probably. That is considered</p> <p>12 background contamination.</p> <p>13 Q Then he goes on to say no diffraction</p> <p>14 patterns were observed, which corresponds to</p> <p>15 diffraction patterns for amphibole asbestos fibers,</p> <p>16 right?</p> <p>17 A Right.</p> <p>18 Q Can we go back to the chart, please.</p> <p>19 Under 9A we have Dr. Pooley, the</p> <p>20 purpose I took straight from the report. Do you see</p> <p>21 that?</p> <p>22 A Yes.</p> <p>23 Q They used an electron microscope, x-ray</p> <p>24 diffraction, Windsor Mine, correct?</p> <p>25 A Yes.</p>	<p>1 Q What they tested was Johnson's Baby Powder</p> <p>2 from batch 344L, correct?</p> <p>3 A Yes.</p> <p>4 Q What they were looking for was, they say</p> <p>5 determine whether asbestos was present in the</p> <p>6 powder, correct?</p> <p>7 A What was your question? I'm sorry.</p> <p>8 Q Let me get it for you. What they used is</p> <p>9 an optical microscope and an electron microscope,</p> <p>10 correct?</p> <p>11 A Yes.</p> <p>12 Q What they concluded was no asbestos or</p> <p>13 asbestiform materials were identified. Only one</p> <p>14 fiber was observed, which could not be identified as</p> <p>15 rolled or folded flakes, correct?</p> <p>16 A Yes.</p> <p>17 Q Can we go to the chart. On the chart</p> <p>18 under 8-19-1971, 9D, we have the author, McCrone,</p> <p>19 optical microscope, electron microscope, correct?</p> <p>20 A Yes.</p> <p>21 Q Johnson's Baby Powder, or JBP I put as an</p> <p>22 abbreviation, batch 344L, correct?</p> <p>23 A Yes.</p> <p>24 Q And I put in quotes, no asbestos or</p> <p>25 asbestiform minerals were identified.</p>

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<p>1 A Yes.</p> <p>2 Q Are we on the same page?</p> <p>3 A Yes.</p> <p>4 Q The next one I have is 27A. 27A was part</p> <p>5 of the cover letter that went to Johnson and</p> <p>6 Johnson -- I mean to the FDA from Johnson and</p> <p>7 Johnson on October 17, 1972, correct?</p> <p>8 A Can you tell me the tab again?</p> <p>9 Q Yes, Ma'am, 27b</p> <p>10 A 27 B, yes.</p> <p>11 Q Actually, I'm looking at the cover letter,</p> <p>12 which is I think just 27, October 17, 1972?</p> <p>13 A I got it, thank you.</p> <p>14 Q Okay.</p> <p>15 A Yes.</p> <p>16 Q And September 8, under A is a report from</p> <p>17 Sperry-Rand to Dr. Goudie, correct?</p> <p>18 A Yes.</p> <p>19 Q He says that what he was doing was</p> <p>20 defining the types of particles which I referred to</p> <p>21 as asbestiform and which more correctly should be</p> <p>22 called fiber form. Do you see that?</p> <p>23 A Yes.</p> <p>24 Q What he used in his testing method was</p> <p>25 x-ray diffraction and an SEM microscope, correct?</p>	<p>1 conclusion, right?</p> <p>2 A Yes.</p> <p>3 Q We are on the same page?</p> <p>4 A Yes.</p> <p>5 Q Okay. The next test I have is in 25C, and</p> <p>6 that's the October 27, 1972 report from the Colorado</p> <p>7 School of Mines Research Institute. Do you see</p> <p>8 that?</p> <p>9 A Yes.</p> <p>10 Q It talks about -- it was to Dr. Goudie,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q And it talks about defining the -- scratch</p> <p>14 that. Determining if serpentine, possible</p> <p>15 chrysotile present. Correct, for the purpose of</p> <p>16 determining if serpentine, possibly chrysotile is</p> <p>17 present?</p> <p>18 A Yes.</p> <p>19 Q They ultimately determined that, here it</p> <p>20 says, "It is probable that the contention that the</p> <p>21 talc samples contain about 3 percent chrysotile is</p> <p>22 mistakenly based on the magnitude of the 7A</p> <p>23 chlorite. If this is so, it could have been avoided</p> <p>24 by step scanning," correct?</p> <p>25 A Yes.</p>
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<p>1 A I don't see where it says that. Can you</p> <p>2 point that out, please?</p> <p>3 Q Sure. If you look on the second page, it</p> <p>4 talks about the scanning electron microscope and the</p> <p>5 x-ray analyzer. Do you see that?</p> <p>6 A Yes, I see that. Thank you.</p> <p>7 Q And what he says is, "Based on the work</p> <p>8 I've done with chrysotile from Johnson's mine Quebec</p> <p>9 form A and C in the drawing have characteristics</p> <p>10 that would indicate they could very well be</p> <p>11 chrysotile." Do you see that part?</p> <p>12 A Yes.</p> <p>13 Q Then he goes on to say, "At the end, the</p> <p>14 scanning electron microscope and x-ray dispersion</p> <p>15 and x-ray analyzer are not able to positively</p> <p>16 identify chrysotile or any form of asbestos.</p> <p>17 However, these tools are very able to identify fiber</p> <p>18 forms which may be asbestos." Correct?</p> <p>19 A Yes.</p> <p>20 Q Can we go back to the chart, please. Do</p> <p>21 you see on the chart we have the date, Sperry-Rand,</p> <p>22 to Dr. Goudie, the purpose, the fact they used SEM</p> <p>23 and XRD and then the quotes we just went over.</p> <p>24 Forms A and C could very well be chrysotile. Then I</p> <p>25 have an ellipsis, I skipped stuff, and then the</p>	<p>1 Q Can we go back to the chart, please. So I</p> <p>2 have under the 10-27, under 25C, use an x-ray</p> <p>3 diffraction, looking at the Johnson Baby Powder lots</p> <p>4 108 and 109T, the quote we just went over. Correct?</p> <p>5 A I can't see.</p> <p>6 Q "It is probable that the contention that</p> <p>7 the two talc samples contain about 3 percent</p> <p>8 chrysotile is mistaken?"</p> <p>9 A Yes, that is correct.</p> <p>10 Q The next one I have 25, the report from</p> <p>11 McCrone dated October 27, 1972. Examination of</p> <p>12 Johnson & Johnson Baby Powder given to Dr. Goudie,</p> <p>13 correct?</p> <p>14 A Yes.</p> <p>15 Q And what they used in this test was x-ray</p> <p>16 diffraction, a light microscope and an electron</p> <p>17 microscope, correct?</p> <p>18 A Yes. X-ray diffraction, light and</p> <p>19 electron, yes.</p> <p>20 Q And therefore, the conclusion states, "A</p> <p>21 few tremolite rods were observed in both samples.</p> <p>22 No chrysotile has been detected." Correct?</p> <p>23 A Yes.</p> <p>24 Q Can we go to the chart, please?</p> <p>25 A Can I just add right before that it says</p>

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<p>1 showed material to be substantially free of 2 asbestiform materials.</p> <p>3 Q Okay. I'll add that in. Shown to be 4 substantially free of asbestiform material. Right 5 after he says substantially free, he says a few 6 tremolite rods were observed in both samples. No 7 chrysotile has been detected. Correct?</p> <p>8 A Yes.</p> <p>9 Q That's now what is on the chart. Are you 10 good with that?</p> <p>11 A Yes.</p> <p>12 Q The next tab I have is the report from 13 Gordon Brown at Princeton concerning Johnson's Baby 14 Powder, lot 108T.</p> <p>15 MR. SMITH: What tab?</p> <p>16 Q Same thing, 25C</p> <p>17 A 25C.</p> <p>18 Q 25C. Are you with me?</p> <p>19 A There's attachment of three reports together.</p> <p>20 Q And what he did is he used x-ray 21 diffraction, correct?</p> <p>22 A Correct.</p> <p>23 Q What he concluded was no evidence of 24 chrysotile or tremolite was found in the x-ray data 25 outlined above, correct?</p>	<p>1 A I think the testing entity is College of 2 Cardiff.</p> <p>3 Q Can we add that in? Other than that, we 4 are good?</p> <p>5 A Yes.</p> <p>6 Q The next test I have was the test that was 7 run by you, Johnson and Johnson, analysis for 8 Johnson's Baby Powder for tremolite asbestos dated 9 September 8, 1972, correct?</p> <p>10 A Yes.</p> <p>11 Q And that was done by Dr. Schelz?</p> <p>12 A Yes.</p> <p>13 Q And he used x-ray diffraction with step 14 scanning, correct?</p> <p>15 A Yes.</p> <p>16 Q And he did the testing on the 108T and 17 109T. Is that correct?</p> <p>18 A Yes.</p> <p>19 Q What he concludes is --</p> <p>20 A Third to the last lie. Samples of Johnson 21 and Johnson Baby Powder do not contain tremolite 22 within the limit of detection.</p> <p>23 Q Of the x-ray diffraction step scanning.</p> <p>24 Okay. Can we now go to the chart the for Schelz.</p> <p>25 Are you good with that, Doctor, the entry on 25C,</p>
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<p>1 A The conclusion is probably easier. It 2 says chrysotile and tremolite impurities proved 3 negative for the chart. If you go down on that page 4 to it is concluded. The last sentence.</p> <p>5 Q A careful search for chrysotile and 6 tremolite impurities proved negative.</p> <p>7 Are we good with that?</p> <p>8 A Yes.</p> <p>9 Q The next is that you identified was a 10 report from Dr. Pooley on those same sample lots, 11 correct, October 31, 1972?</p> <p>12 A Correct.</p> <p>13 Q And he, Dr. Pooley, used x-ray diffraction 14 and differential thermal analysis. Correct?</p> <p>15 A Correct.</p> <p>16 Q Are you with me? It is right on the front 17 page.</p> <p>18 A Yes, I got it.</p> <p>19 Q He says in his conclusion, "No chrysotile 20 is present in the samples of Johnson's Baby Powder 21 at the minimum level detectable by DTA." Correct?</p> <p>22 A Yes.</p> <p>23 Q Back to the chart. On the chart under 24 10-31-72, by Dr. Pooley, you agree with those 25 entries?</p>	<p>1 line 11, "The samples of Johnson's Baby Powder do 2 not contain tremolite within the limit of detection 3 of the x-ray diffraction step scanning technique?"</p> <p>4 A Yes.</p> <p>5 Q The next entry I have to look at is in tab 6 31, and that's under the cover letter of May 25, 7 1973. Are you with me?</p> <p>8 A Yes.</p> <p>9 Q And that attaches a report of baby powder 10 by Dr. Buerger -- I'm sorry, to Shower to Shower, 11 correct?</p> <p>12 A Yes.</p> <p>13 Q Dr. Buerger did x-ray diffraction 14 in his testing?</p> <p>15 A Yes.</p> <p>16 Q And he concludes at the end, "The 17 following impurities were determined not to be 18 present in detectable amounts. Chrysotile asbestos, 19 tremolite, antigorite, Musgravite (ph.), whatever 20 that is, fopcopite (ph.) quartz and dolomite." Got that?</p> <p>21 A Yes.</p> <p>22 Q On the bottom it says a little footnote 23 108T and 109T, correct?</p> <p>24 A Yes.</p> <p>25 Q Can we go to the chart under 5-25-73 and I</p>

<p style="text-align: right;">Page 272</p> <p>1 have the report by Dr. Buerger using x-ray 2 diffraction, looking at Johnson's Baby Powder, 108T 3 and 109T and then the quote is directly from the 4 conclusion. Are you good with that? 5 A Yes. 6 Q The next one I have is under tab 36. 7 There's a report from Gordon Brown at Princeton 8 concerning Shower to Shower using x-ray diffraction, 9 correct? 10 A Correct. There was one before that, the 11 Buerger analysis. 12 Q Let's finish this one and we will go back. 13 A Okay. 14 Q This one says no evidence for chrysotile 15 or tremolite was found, fair? 16 A Yes. 17 Q Dr. Buerger was 31. Is that the one I 18 missed? 19 A Buerger, September 21, 1972. 20 Q What tab? 21 A I'm sorry. 36, right before the Gordon 22 Brown report. 23 Q October 7, 1972? 24 A Yes. 25 Q Are there actual results of testing here?</p>	<p style="text-align: right;">Page 274</p> <p>1 A Thank you. I was confused. The SPS, I 2 thought that was supposed to be XRD. I got the two 3 confused. 4 Q Now we are on this and we are talking 5 about the McCrone Shower to Shower report? 6 A Yes. 7 Q That was done by Dr. Stewart and they used 8 a number of methods, including XRD, TEM, PLM and 9 SEM, correct? 10 A Yes. 11 Q On page 6 of the report, as support for 12 their conclusions, they quote from a report from 13 Sperry-Rand and one from the University of 14 Minnesota. Do you see that? 15 A Yes. 16 Q What they conclude says, "An extensive 17 examination of samples of Johnson and Johnson 18 product, Shower to Shower using x-ray diffraction, 19 light microscopy, scanning electron microscopy, 20 transmission electron microscopy and electron 21 diffraction, has shown this product is free from 22 asbestos or asbestiform minerals. I report that 23 chrysotile was present in a sample from the batch 24 1501Z was erroneous and most likely a 25 misidentification for a form or quota." Do you see</p>
<p style="text-align: right;">Page 273</p> <p>1 I didn't see them. 2 A I think you just re-reviewed Lewin's data. 3 Q But no new testing? 4 A I'm checking. This is a review of the 5 other data. It is not additional data. You are 6 correct. 7 Q Can we go back to tab 36. I want to 8 finish all this before lunch. I promise. Hopefully 9 this afternoon will be less boring. 10 Can we go back to tab 36? Can we go 11 to the chart, please. On 36, 11-9-73 by Brown, 12 x-ray diffraction of Shower to Shower. "No evidence 13 for chrysotile or tremolite in Lewin sample was 14 found," fair? 15 A Yes. 16 Q The next report I have, still under 36, is 17 a June 22, 1973 report from McCrone about Shower to 18 Shower, correct? 19 A Can we go back one second to the Princeton 20 results? 21 Q Sure. 22 A On the chart. 23 Q Which Princeton results? 24 A The ones we just put into the chart. 25 Q Okay. Go ahead.</p>	<p style="text-align: right;">Page 275</p> <p>1 that? 2 A Yes. 3 Q Can we go to the chart, please. On the 4 chart I have the tab 36, they used XRD, TEM and PLM, 5 SEM of Shower to Shower, right? Rather than do the 6 whole thing I just wrote quote Sperry-Rand and 7 University of Minnesota as negative test, correct? 8 A I'm not sure that's quite right. I think 9 what they are saying is scanning electron microscopy 10 is not an appropriate test. 11 Q Can I just say quote Sperry-Rand and 12 University of Minnesota and leave it at that? 13 A If that's of some value. 14 Q I want to come back to that. 15 Then I went right to the conclusion 16 and took the quote from the conclusion, an extensive 17 examination of the samples has shown. Do you see 18 that? 19 A Yes. 20 Q You are good with that? 21 A Yes. 22 Q The very next page is September 7, 1972, 23 test result from the Colorado School of Mines 24 Research Institute. Got it? 25 A Yes.</p>

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<p>1 Q They used x-ray diffraction, looking at 2 Shower to Shower, correct? 3 A Yes. 4 Q And what they said was, "The above data 5 does not indicate the presence of chrysotile." 6 Correct? 7 A Yes. 8 Q Can we go to the chart, please. Does this 9 accurately reflect what we just went through? 10 A Yes. 11 Q Now, lastly in this group, actually two 12 more, there is a test from Dr. Pooley sent to Dr. 13 Goudie dated September 29, 1972, correct? 14 A Yes. 15 Q And they looked at Shower to Shower? 16 A Yes. 17 Q And Dr. Pooley actually doesn't give any 18 results, right? What he says is, "The positive 19 identification of chrysotile can only be made with a 20 transmission electron microscope because it is with 21 this instrument that the fiber can be observed and 22 defined." Correct? 23 A Yes. 24 Q Can we go to the chart, please, under 25 9-29-72 for Dr. Pooley. Does that accurately</p>	<p>1 Q And you used x-ray diffraction? 2 A Yes. Differential thermal analysis. 3 Q Differential thermal analysis, and your 4 conclusion was what? 5 A No chrysotile detected in Shower to 6 Shower. 7 Q Can we go to that and make sure we have it 8 as Dr. Nicholson stated. 9 A I'm reading this off of the paper, so I 10 don't think you need to quote me. 11 Q I want to make sure we get the quote you 12 want. 13 MR. SMITH: Objection. 14 A It says no chrysotile by DTA, there was no 15 chrysotile detected in Shower to Shower. 16 Q Okay. So let me go to -- 17 A There's the x-ray diffractometer scans of 18 Shower to Shower from the J & J results also say 19 absence of chrysotile in this talc. Because he used 20 two methods. 21 Q So we should make sure it says XRD and 22 what? 23 A On page 2 of the memo at the top it says 24 the continuous x-ray diffractometer scans of Shower 25 to Shower powder exhibited by Dr. Lewin indicate the</p>
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<p>1 reflect what we just went through? 2 A Yes, but that's not a result of a test. 3 It is an opinion about the method. 4 Q Is that good? 5 A Yes. 6 Q Under that same tab, 9-28-72 is a testing 7 result by Johnson and Johnson itself, correct? 8 A You skipped -- I'm a little confused. You 9 skipped the Carnegie Mellon letter. 10 Q Okay. Let's go through that. 11 A And I say that I don't think it is test 12 results, it is people commenting on Lewin's letter 13 was referencing. 14 Q What would you like me to put on the chart 15 for Carnegie Mellon? 16 A I think that Pooley results shouldn't be 17 on the chart. It is fine the way you put them in 18 now. Just as Dr. Lewin was wrong, so we can move 19 on. 20 Q We can skip it? That's no news. You 21 always thought he was wrong, right? 22 A Not what I thought. He was wrong. 23 Q 9-28-72 is the analysis of Shower to 24 Shower done by Johnson and Johnson, correct? 25 A Correct.</p>	<p>1 absence of chrysotile in this talc. This is evident 2 from the lack diffraction, blah, blah, blah. 3 There are saying they are confirming 4 by x-ray diffraction that there's no chrysotile and 5 then below the last three of lines it says by DTA 6 there's no chrysotile detected in Shower to Shower 7 powder at the proposed level of two percent by Dr. 8 Lewin. 9 Q So let's go to the chart and make sure we 10 have exactly what you want in the chart. Under 11 method it should say XRD and DTA? 12 A Yes. 13 Q And then we have down here the absence of 14 chrysotile in the talc. What else do you want? 15 A It says absence by x-ray diffractometer, 16 so XRD, absence of chrysotile. 17 MR. PLACITELLA: It is 12:30. Do you 18 want to break for lunch and we will finish up 19 whatever is need to? 20 THE VIDEOGRAPHER: The time is 12:35. 21 We are going off the video record. 22 23 (Luncheon recess taken) 24 25 THE VIDEOGRAPHER: The time is</p>

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<p>1 1:32 p.m. We are now back on the video record. 2 Counselors, you may proceed. 3 4 BY MR. PLACITELLA: 5 Q Doctor, I'm going to your tab 45. By the 6 way, do you know why there are like numbers missing 7 in this book? 8 A No, I don't. 9 Q Like there's no 51. So the record is 10 clear, not all the numbers are in here, 1 through 11 whatever? 12 A I never noticed that, but you are right, 13 there are missing tabs. 14 Q I wanted to make sure. So, I'm looking at 15 tab 45 that you flagged, which is a October 4, 1974, 16 letter from Schelz to Schultz at the FDA. This is 17 about results from round robin test, right? 18 A Yes. 19 Q Do you recall that the round robin tests 20 were actually blind tests that different companies 21 got to test methodology? 22 A Yes. 23 Q There's no indication here on this 24 particular document that what this refers to is 25 actually a Johnson and Johnson product, correct?</p>	<p>1 A Yes. The one addition is George Stadlin 2 from Bristol Myers was actually the chairman of 3 CTFA talc subcommittee. 4 Q And J & J was part of that, right? 5 A That is correct. 6 Q So where it talks here on the second page, 7 you pointed out to me Johnson and Johnson, 150 8 samples all done by Pooley, right? 9 A Yes. 10 Q Do you see that? 11 A Yes. 12 Q There's no product here specified as to 13 what exactly he was testing, right? 14 A That is correct. This is a summary of 15 what tests had been done. I believe that's what the 16 summaries of analyses were sent. I believe that's 17 what this letter refers to. 18 Q On this particular document we don't know 19 if any of these tests were of Johnson and Johnson 20 products, correct? 21 A It doesn't explicitly say that, but it 22 does imply that they are from Johnson and Johnson. 23 You are correct. It doesn't list the sample names 24 and pedigree of those samples. 25 Q I'm going to get to that. It doesn't give</p>
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<p>1 These were blind tests? 2 A I'm sorry, I didn't understand the 3 question. 4 Q Sure. Blind test, what happened with the 5 round robin, as I understand it, is there were a 6 select group of samples that were sent to various 7 people to do testing, including Johnson and Johnson. 8 They were blind. Nobody knew the source of the 9 samples, other than the person who was handing them 10 out. Are you with me? 11 A Yes. 12 Q So we can't tell from looking at this 13 report whether the test referred to here is actually 14 of a Johnson and Johnson product. 15 A I only see talcum powder number 3, so I 16 don't know the exact source of that powder. That's 17 correct. 18 Q If you figure it out at some point, I'm 19 happy to put it on the chart. Right now I'm going 20 to leave it off, if that's okay with you. 21 A That's fine. 22 Q The next tab I think these are all 23 related that you flagged was tab 52, and that was a 24 September 12, 1975 letter from Bristol Myers to the 25 FDA. Are you with me?</p>	<p>1 the method that was used to do the analysis here, 2 does it? 3 A No, it does not. 4 Q I think the answer is a little further 5 down. This talks about -- this particular document 6 talks about various attachments, including the 7 attachments from Johnson and Johnson, correct? 8 A Yes. 9 Q It says right underneath it, I have 10 included the attachments, right? 11 A Yes. They are in the subsequent tabs. 12 Q And then you have all the tabs that were 13 attachments, correct? 14 A Yes. 15 Q If you go to the attachment under I, 16 there's a May 20, 1975 letter from Pooley to Johnson 17 and Johnson, correct? 18 A Yes. 19 Q What he says is, "In reply to your 20 question concerning how many talc specimens we have 21 examined over the past few years, we have arrived at 22 the following figures," and he talks about getting 23 it from 30 different geographical sources, correct? 24 A Correct. 25 Q And he says, "If you put them all</p>

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<p>1 together, that would have come up with about 150 2 samples," right? 3 A Correct. 4 Q That's the same number that is in the 5 Bristol Myers Squibb letter, correct? 6 A Yes, correct. 7 Q Johnson and Johnson didn't get talc for 8 use in the United States from 30 different 9 geographical sources, correct? 10 A Well, I can't answer that directly because 11 geographical sources could mean different areas of a 12 single mine or different areas of several mines. 13 Dr. Pooley did a survey of both of 14 them, the Vermont mine and Italian mine. Maybe it 15 is referring to that. 16 Q I think there's more information that will 17 help us through this. 18 So then if I go to tab J, which is 19 the April 29, 1975 letter from Johnson and Johnson 20 to the CTFA, the man that wrote the letter at 21 Bristol Myers. Do you see that? 22 A Yes. 23 Q What Johnson and Johnson says is, "Our 24 scientists and consultants have conducted numerous 25 studies on the purity level of cosmetic talc grades</p>	<p>1 A Not correct. Italy and the United States 2 are both listed here. 3 Q You are right. I'm sorry. 4 A We have a worldwide talc business, which 5 could have included mines in these other geographic 6 sites. 7 Q But you weren't getting talc from Brazil 8 and putting it in talc that was sold in New Jersey, 9 right? 10 A No. 11 Q So then if we go to attachment B, which 12 was also referred to in your list, do you see Dr. 13 Pooley's summary report? 14 A Yes. 15 Q There's an attachment B. This is what 16 Pooley did, right? 17 A Yes. 18 Q And you remember in the original letter to 19 the FDA it referred to the results of Pooley, 20 correct? 21 A Yes. 22 Q Here we say if you want to go to Pooley's 23 report, go to attachment B, correct? 24 A Yes. 25 Q If I go to attachment B, Pooley states,</p>
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<p>1 from both domestic and worldwide sources." Do you 2 see that? 3 A Yes. 4 Q Then further down it talks about since 5 1972, and it talks about who did the test. Do you 6 see that? 7 A Yes. 8 Q And some of them include the entities that 9 we have gone through already today, Colorado School 10 of Mines, Professor Brown, Professor Buerger, 11 correct? 12 A Yes. 13 Q Then it says on the bottom, "Further 14 details of the country of origin and the method of 15 analysis are described in attachment A." Do you see 16 that? 17 A Yes. 18 Q Then if you go to attachment A, which is 19 tab K, it gives the country of origin and it lists 20 Italy, Indian, USA, Korea, Brazil, Australia, 21 Pakistan, China and Austria, correct? 22 A Yes. 23 Q Out of this entire list, the only mine 24 that potentially was a supplier for talc used in the 25 United States was Italy, correct?</p>	<p>1 "Over the past two years we have engaged in an 2 extensive study of samples of cosmetic talc from 3 various parts of the world." That's consistent, 4 correct? 5 A Yes. 6 Q And it says, "A number of these samples 7 are imported at regular intervals into the United 8 Kingdom," correct? 9 A Yes. 10 Q Samples have been received and examined 11 from the following countries. And here he lists 12 Italy, France, India, South Korea, China, Zambia, 13 Austria, Brazil and Pakistan, correct? 14 A Yes. 15 Q Again, on the next page he talks about the 16 talcs he is testing were used in the United Kingdom, 17 correct, and he actually states on the bottom, "The 18 mineralogical investigations have come up cosmetic 19 grade talc powders entering the United Kingdom has 20 not been confined to single batch samples. Many of 21 the patterns have been examined over a period of 22 time from independent shipments." Do you see that? 23 A Yes. 24 Q So Dr. Pooley's report is not about talc 25 that was used necessarily in the United States. It</p>

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<p>1 was talc that was used in the United Kingdom, right?</p> <p>2 According to his report. His report is all about</p> <p>3 stuff that was used in Great Britain.</p> <p>4 A That's what it says. They were used in</p> <p>5 the United Kingdom.</p> <p>6 Q So when you were referring in 52, when</p> <p>7 this letter talks about the samples done by Dr.</p> <p>8 Pooley, which he said were all negative for</p> <p>9 chrysotile?</p> <p>10 A Yes.</p> <p>11 Q What he was talking about was the samples</p> <p>12 that he looked at of talc that was used in the</p> <p>13 United Kingdom, right?</p> <p>14 A Yes.</p> <p>15 Q So in terms of testing that I'm going to</p> <p>16 put on the chart for talc that was used in the</p> <p>17 United States and sent to places like New Jersey,</p> <p>18 I'm not going to include that. Okay?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A So to go back to the list, Dr. Pooley was</p> <p>21 in the United Kingdom, so it makes sense he would be</p> <p>22 using cosmetic talcs shipped to the United Kingdom.</p> <p>23 I'm looking at the details in the</p> <p>24 context of your question, but we do have Italy and</p> <p>25 we know we sourced Italian talc in the U.S. and we</p>	<p>1 talc shipment is routinely examined for asbestos.</p> <p>2 The number of analysis appears low, however."</p> <p>3 Correct?</p> <p>4 A Yes. That's what it says.</p> <p>5 Q Then the next paragraph says, "Johnson and</p> <p>6 Johnson also reported the analysis of American and</p> <p>7 British talc products based upon a cooperative study</p> <p>8 between Dr. Langer and Dr. Pooley. This study</p> <p>9 involved 19 samples analyzed by Langer, of which ten</p> <p>10 samples were implicated to contain asbestos."</p> <p>11 Correct?</p> <p>12 A Yes.</p> <p>13 Q Can we tell from looking at this whether</p> <p>14 these were actually samples of Johnson and Johnson?</p> <p>15 A We don't know that for sure, but we know</p> <p>16 that Langer said they were Johnson and Johnson talc.</p> <p>17 Q Okay. And it says, "Wherever Langer</p> <p>18 reported tremolite and anthophyllite, Dr. Pooley only</p> <p>19 found anthophyllite." Correct?</p> <p>20 A Correct.</p> <p>21 Q And they go on to say, "That these tests</p> <p>22 were done on samples and done in 1973." Correct?</p> <p>23 A Yes.</p> <p>24 Q So if we were going to go to the chart and</p> <p>25 we were going to add this one, we would have</p>
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<p>1 also have U.S. sourced talc.</p> <p>2 Because it is used in the United</p> <p>3 Kingdom doesn't mean it is not relevant to the FDA.</p> <p>4 So whether you want to add it to your chart or not</p> <p>5 doesn't matter to me.</p> <p>6 Q All I want to try to put in the chart is</p> <p>7 tests that we know were done on cosmetic talc or the</p> <p>8 source that was definitely used in the United</p> <p>9 States. We can't say that for certain from all</p> <p>10 this. Do you agree?</p> <p>11 A That's true.</p> <p>12 Q Then the last reference you had was on tab</p> <p>13 56, and that was in a March 18, 1976 -- and that was</p> <p>14 actually a memo that was an internal memo at the</p> <p>15 FDA, correct?</p> <p>16 A That is correct.</p> <p>17 Q The subject is asbestos in talc, correct?</p> <p>18 A Proposed regulation, yes.</p> <p>19 Q Under Johnson and Johnson, it talks about</p> <p>20 tests that were done in 1972 and 1973. Did you see</p> <p>21 that using XRD?</p> <p>22 A Yes.</p> <p>23 Q And sometimes TEM, correct?</p> <p>24 A Yes.</p> <p>25 Q And what the FDA says is, "Allegedly every</p>	<p>1 3-18-1976, we would say Pooley and Langer, or do you</p> <p>2 want me to say as reported by? What do you want me</p> <p>3 to put as the source?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A At the source, meaning the source of the</p> <p>6 samples?</p> <p>7 Q Whoever did the test. Should we put</p> <p>8 Pooley and Langer?</p> <p>9 A Yes.</p> <p>10 Q Pooley and Langer, 1973, correct?</p> <p>11 A Correct.</p> <p>12 Q And I guess we will just quote it so it is</p> <p>13 clear, right? It says, "This study involved the 19</p> <p>14 samples analyzed by Dr. Langer, of which ten samples</p> <p>15 were implicated to contain asbestos. Wherever Dr.</p> <p>16 Langer reported tremolite and anthophyllite, Dr.</p> <p>17 Pooley only found anthophyllite."</p> <p>18 A It says Dr. Pooley did not find --</p> <p>19 Q I'm still going. "Dr. Pooley did not</p> <p>20 find asbestos in those samples where Dr. Langer</p> <p>21 determined asbestos at concentrations at less than 5</p> <p>22 percent i.e., Dr. Pooley implicated only five</p> <p>23 samples." Are we good?</p> <p>24 A I don't think this is clear at all. The</p> <p>25 next sentence says about British talc samples.</p>

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<p>1 Are they saying it was British talc samples in which 2 they thought they might have seen anthophyllite? I 3 think the results here are unclear. I do know that. 4 Q Why don't we put the whole quote in? 5 A You can put the whole thing in. I think 6 it is still not clear. 7 Q Anthophyllite is asbestos. We know that, 8 right? 9 A No, that's not true. 10 Q Not true? 11 A No. You can have non -- most of 12 anthophyllite is not asbestos. 13 Q But it doesn't say here one way or the 14 another? 15 A Exactly my point. 16 Q But what they were testing for was 17 asbestos, right, because the subject here is 18 asbestos in talc, right? 19 MR. SMITH: Objection. 20 A Correct, but to really understand the 21 context of this, it is important to know what Langer 22 found and Langer was with Pooley specifically as 23 they were determining what the appropriate methods 24 were. He was there basically learning from Dr. 25 Pooley.</p>	<p>1 never gave the FDA an asbestos test results 2 concerning the talc after 1973. 3 MR. SMITH: Objection. 4 A According to the records here, it does not 5 appear to be. I would like to look at the table 6 where you put all the dates in, please. 7 Q As soon as she is done typing we will go 8 through it. 9 A Whatever the last date on is on here I'm 10 not aware of communications with any other asbestos 11 testing done by Johnson and Johnson that was on 12 Johnson and Johnson's behalf given to the FDA. 13 Q When you want to see the next screen, let 14 me know. 15 A Go ahead. Go down. That's correct. 16 Q So Johnson and Johnson never provided the 17 FDA any asbestos test results on the cosmetic talc, 18 according to your records, after 1973. Correct? 19 A That is correct. 20 Q Now, I want to go back and I looked at 21 your notes and your other binders and I want to get 22 -- you keep talking about context. So I want to 23 talk about context of how and why these tests were 24 done, because I know you want to talk about that. 25 MR. SMITH: Objection.</p>
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<p>1 Q I get that. So should I take this off the 2 chart? I'll do whatever you want. Take it off the 3 chart all together or I'll write the quote in and 4 somebody will figure it out later. How is that? 5 MR. SMITH: Objection. 6 A You can do that. This is very unclear to 7 me. 8 Q While Carolyn is doing that, if I look at 9 all of the samples, and we have gone through 10 everything now, correct, everything you have tabbed? 11 A I believe so. 12 Q So if I look at all of the test results 13 that were provided to the FDA, it would appear that 14 there was no test result on Johnson and Johnson talc 15 that post dated 1973, correct? 16 A I would have to go back and look at the 17 list, but if I may, during this time much of this 18 analysis was around determining what the appropriate 19 methods were. 20 The J41 standard was being developed. 21 The FDA had proposed their standard, so -- 22 Q I get all that. All I'm asking you is the 23 following. From a review of the book and everything 24 we have gone through now for the better part of the 25 day, according to your records, Johnson and Johnson</p>	<p>1 Q Are you with me? 2 A I'm with you. I think it is important to 3 understand the information. 4 Q In your notes, and I think in the binder 5 you had, you had references to Johnson and Johnson's 6 involvement with Dr. Irving Selikoff and the Mt. 7 Sinai School of Medicine. Do you recall that? 8 A Yes, in the early '70s. 9 Q How that started was that there was a 10 publication by the Tenovus Institute in the open 11 medical literature that found talc in women's 12 ovaries and in the tumors in their ovaries, correct? 13 A I can't answer that directly because there 14 were several things going on at that time. I can't 15 say there was a cause and effect of that Tenovus 16 paper. 17 Q J10 is an article entitled Talc and 18 Carcinoma of the ovary and cervix from the Tenovus 19 Institute for Cancer Research. Do you see that? 20 A Yes. 21 Q You have seen this before, correct? 22 A Yes. 23 Q What happened here was they studied tissue 24 that was obtained from patients with cancer of 25 either ovary or the cervix. Correct?</p>

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<p>1 A Correct.</p> <p>2 Q In the results they said they didn't find</p> <p>3 any asbestos particles, but they did find talc in</p> <p>4 75 percent of the tumors that they looked at,</p> <p>5 correct?</p> <p>6 A Correct, and in approximately half of the</p> <p>7 normal tissue that they looked at.</p> <p>8 Q Okay. In the article they actually had</p> <p>9 pictures of the talc they found in the tumors,</p> <p>10 correct?</p> <p>11 A Correct.</p> <p>12 Q At the end of the article they -- scratch</p> <p>13 that.</p> <p>14 They also raise the issue of</p> <p>15 asbestos, although they didn't find any in this</p> <p>16 examination, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A They do write that in the paper in the</p> <p>19 discussion.</p> <p>20 Q Then what happens is that Johnson and</p> <p>21 Johnson goes to see Dr. Selikoff at Mount Sinai</p> <p>22 because of his reputation in the area, and asks for</p> <p>23 his help in actually looking at the tissue from</p> <p>24 these woman, correct?</p> <p>25 A That's correct.</p>	<p>1 Institute.</p> <p>2 Q It says Dr. Selikoff was prepared to help</p> <p>3 and you paid him, right?</p> <p>4 A I would assume so, yes.</p> <p>5 Q So he went to work for you.</p> <p>6 A I think that implies he would work for us</p> <p>7 as opposed to doing scientific work.</p> <p>8 Q Fair enough. And you define in your memo</p> <p>9 what exactly you are setting out to do. You say,</p> <p>10 "You should give serious considerations to</p> <p>11 initiating appropriate steps to developing</p> <p>12 scientific information and answer a number of</p> <p>13 questions raised, including whether talc does indeed</p> <p>14 get distributed in tissues of people using the</p> <p>15 products, and then assessing whether the talcs are</p> <p>16 of the type used in the pharmaceutical industry, and</p> <p>17 if so, are harmful to tissues." Correct?</p> <p>18 A Yes.</p> <p>19 Q Then it talks about paying Dr. Selikoff,</p> <p>20 right?</p> <p>21 A Yes.</p> <p>22 Q And copied on the memo to memorialize the</p> <p>23 meeting are a number of Johnson and Johnson key</p> <p>24 executives, correct?</p> <p>25 A Individuals from Johnson and Johnson. I</p>
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<p>1 Q When Johnson and Johnson went to see Dr.</p> <p>2 Selikoff, everything started out friendly, correct?</p> <p>3 A I wasn't there, but I assume so.</p> <p>4 Q They were there to get Dr. Selikoff's</p> <p>5 help, correct?</p> <p>6 A That is correct.</p> <p>7 Q And in this memo from April 30, 1971,</p> <p>8 which is up on the screen, it is actually a memo</p> <p>9 concerning the meeting with Dr. Selikoff, right?</p> <p>10 A Yes.</p> <p>11 Q And it talks about having the meeting with</p> <p>12 Dr. Selikoff and talking to him about actually doing</p> <p>13 work on what was found by the Tenovus Cancer</p> <p>14 Institute in Wales, correct?</p> <p>15 A Yes.</p> <p>16 Q It talked about the one of the reasons</p> <p>17 they went to see Dr. Selikoff is because of his</p> <p>18 expertise and his work with the American Cancer</p> <p>19 Society and his publications, correct?</p> <p>20 A Yes.</p> <p>21 Q And what ended up happening at that</p> <p>22 meeting is that Dr. Selikoff actually agreed to go</p> <p>23 to work for Johnson and Johnson, correct?</p> <p>24 A I wouldn't characterize it like that, but</p> <p>25 he did agree to look at tissues from the Tenovus</p>	<p>1 would not necessarily categorize them as key</p> <p>2 executives.</p> <p>3 Q Doctors, scientists, executives.</p> <p>4 A Scientists, research and development</p> <p>5 professionals.</p> <p>6 Q Fair enough.</p> <p>7 A And then, somehow, Johnson and Johnson</p> <p>8 obtained the actual tissue of these women from Great</p> <p>9 Britain and brought that to the United States.</p> <p>10 Correct?</p> <p>11 A I would disagree with the characterization</p> <p>12 of that. The Tenovus Institute agreed to</p> <p>13 collaborate and share their tissues. So Dr.</p> <p>14 Selikoff and Johnson and Johnson could also examine</p> <p>15 them.</p> <p>16 Q Right.</p> <p>17 A So we didn't somehow obtain them. It was</p> <p>18 a collaboration. Everybody was quite open about</p> <p>19 sharing the tissue.</p> <p>20 Q How did you get tissue from -- how did you</p> <p>21 get permission to look at tissue from these women's</p> <p>22 bodies? How did you get that?</p> <p>23 A I don't know what the process was in 1971,</p> <p>24 so I couldn't answer that specifically.</p> <p>25 Q Didn't you have to get permission from the</p>

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<p>1 women if you were going to look at what's in their 2 bodies?</p> <p>3 A I don't know what the process was in 1971 4 for obtaining consent from women. I'm sure the 5 folks at Tenovus followed whatever the appropriate 6 processes were.</p> <p>7 Q Then what happened was that, however you 8 got the women's tissue to the United States, you 9 made sure it was delivered to Dr. Selikoff, correct?</p> <p>10 A It may have been mailed directly to Dr. 11 Selikoff, but I know he received tissue from the 12 Tenovus Institute.</p> <p>13 Q That's like a lot of power, right? You 14 see tissue, talc in somebody's tissue in Great 15 Britain and then all of a sudden would you arrange 16 and have it in a hospital in the United States. I 17 couldn't do that, could I?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I would hope not. Because this is a 20 scientific exchange and this is common. If you have 21 something unusual it is very common to have another 22 laboratory, an expert in this case, the world's 23 expert, look at that tissue as well.</p> <p>24 Q He was the world's expert, correct?</p> <p>25 A At that moment in time in asbestos and</p>	<p>1 Q And to observe the preparation of the 2 tissue that was received from the Tenovus Institute 3 for an examination with electron microscope, 4 correct?</p> <p>5 A Yes.</p> <p>6 Q Someone from Johnson and Johnson was 7 actually there observing Dr. Selikoff do his 8 analysis, correct?</p> <p>9 A Yes.</p> <p>10 Q It says, "The subject of asbestos in 11 Johnson's Baby Powder from Dr. Langer's point of 12 view was also explored." Do you see that?</p> <p>13 A Yes.</p> <p>14 Q Then below it it talks about what Johnson 15 and Johnson observed. They observed the analysis of 16 the Tenovus samples, correct?</p> <p>17 A Correct.</p> <p>18 Q And the samples were prepared using the 19 method that are was used by Johnson and Johnson's 20 expert, Dr. Pooley, correct?</p> <p>21 A Correct.</p> <p>22 Q Then after they did this they actually put 23 the tissue under a microscope while Johnson and 24 Johnson was watching, correct?</p> <p>25 A That is correct.</p>
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<p>1 tissue, yes, he was.</p> <p>2 Q And when he looked at the tissue, he found 3 chrysotile asbestos in the tissue of the women that 4 you arranged to have examined by him, correct?</p> <p>5 A I'll disagree with your characterization. 6 Firstly, we didn't get the tissue from the women. 7 It was part of a study in the Tenovus Institute.</p> <p>8 And secondly I'm not aware that he 9 found chrysotile in that tissue, which was also 10 tested at Johnson and Johnson's labs, and there's a 11 lot more to the story than just Dr. Selikoff and 12 them examining the tissue.</p> <p>13 Q I'm going to get the whole story out. 14 That's my objective. If you think I'm missing 15 something, either you tell me or your lawyer will 16 bring it out. Can we agree?</p> <p>17 A Yes.</p> <p>18 Q J & J 17 is entitled, Meeting With Dr. 19 Langer on July 9th concerning Analytical Analysis of 20 Talc. Are you with me?</p> <p>21 A Yes.</p> <p>22 Q And it talks about Johnson and Johnson 23 visiting with Dr. Langer at Mount Sinai on July 9th, 24 correct?</p> <p>25 A Yes.</p>	<p>1 Q And then it says, "Viewing the grid 2 prepared on Friday, and it gives the magnification, 3 we were unable to find any particles which could 4 obviously be identified as talc. However, fibrous 5 structures were observed under higher magnification, 6 30,000 and up." Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Where it says we did this, it says, "These 9 fibers were identified by Dr. Langer as chrysotile." 10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And it says, "Method of identification is 13 based upon his experiences in observing the fibers 14 of pure chrysotile under similar experimental 15 conditions. The characteristic density profile 16 across the diameter of the fibers is observed at 17 high magnification and indicates the presence of 18 tubular chrysotile." Do you see that?</p> <p>19 A Yes, I do.</p> <p>20 Q There's nothing in this memo where Johnson 21 and Johnson is taking exception to what is being 22 observed while they are standing there, correct?</p> <p>23 A I don't see that, no.</p> <p>24 Q And so with Johnson and Johnson standing 25 there while Dr. Langer is looking at the tissue</p>

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<p>1 samples, Dr. Langer identifies chrysotile asbestos 2 in the tissue samples of the women who were studied 3 at the Tenovus Institute, correct? 4 A It appears he has found chrysotile, but I 5 know Dr. Langer was not able to identify chrysotile 6 in other materials, so I don't know what kind of 7 follow up there was to this memo. 8 Q All I'm asking you about is this memo. 9 in this memorandum, written by Johnson and Johnson 10 they report while they were standing there, that Dr. 11 Langer found chrysotile asbestos in the tissue of 12 the women, correct? 13 A Yes. This says Dr. Langer appears to 14 think he found chrysotile. 15 Q It doesn't say appears to think he found. 16 It says, "were identified as chrysotile by Dr. 17 Langer." Correct? 18 A Correct. 19 Q And then it goes on to state that he also 20 used a light microscopy and an electron microscope 21 looking at Johnson's Baby Powder. Correct? 22 A Correct. 23 Q And what he found, in part, was fibrous 24 content that varied from sample to sample. That is 25 what you report, correct?</p>	<p>1 A That is correct. 2 Q And then in the conclusion, in the summary 3 that Johnson and Johnson writes, they state, "In the 4 uterus sample from Tenovus, chrysotile, rather than 5 talc, was found. 2, chrysotile is identified in the 6 electron microscope scope by it is characteristic 7 tubular appearance at high magnification." Did I 8 read that correctly? 9 A You did. 10 Q And then in the fourth paragraph you 11 state, "Electron microscopy at high magnification 12 shows a few fibers to be present in Johnson's Baby 13 Powder, which can be identified with chrysotile 14 asbestos, according to Dr. Langer. No 15 quantification was performed." Correct? 16 A That is what it says, yes. 17 Q And what happened next was that within a 18 couple of weeks Dr. Selikoff and Dr. Langer reported 19 what they found in the press, correct? 20 A I believe it was a different results they 21 reported in the press but, yes. 22 Q These are documents when we got from 23 Johnson and Johnson. I didn't go out and find them, 24 just so you know. 25 So in here I put up on the screen is</p>
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<p>1 A That's what he indicated he observed. 2 That's what is in the memo, correct. 3 Q And then it states that he used an 4 electron microscope with Johnson and Johnson 5 standing there, correct? 6 A Correct. 7 Q And that, "using the electron microscope, 8 Dr. Langer had demonstrated to me the presence of 9 some very fine fibers at moderately high 10 magnification which he identifies as chrysotile 11 material asbestos by the typical tubular appearance 12 of the fiber." Correct? 13 A Yes, I see that. 14 Q And there's nothing in this memo that 15 takes exception to that, correct? 16 A Not in this memo, but there's a lot of 17 information outside this memo that would call into 18 question Dr. Langer's abilities to identify 19 asbestos. 20 Q Ma'am, when Johnson and Johnson was 21 sitting there watching Dr. Langer do these tests, 22 and they reported it back to the executives at 23 Johnson and Johnson, nowhere in the memo did they 24 question the findings of Dr. Langer, correct? 25 MR. SMITH: Objection.</p>	<p>1 one of those press articles, correct? 2 A I don't know. One of which press 3 articles? 4 Q Articles that were collected by Johnson 5 and Johnson about statements that were made by Mount 6 Sinai or Dr. Selikoff in the press about what he 7 found. 8 MR. SMITH: Objection. 9 A About what he found. This is a separate 10 topic with Dr. Kretchmer in the Environmental 11 Protection Agency. 12 Q Okay. You are right. This is out of 13 context. I'll come back to this. 14 (Exhibit J&J-24) After Johnson and 15 Johnson watched Dr. Langer do his test, Dr. Langer 16 wrote to Johnson and Johnson on November 10, 1971 17 and said, "We found asbestos in the tissue that you 18 sent us." Correct? 19 A Yes. 20 Q And he said, "We also looked at your 21 samples and we determined that the talc was fibrous 22 and that was chrysotile in your baby powder." 23 Correct? 24 A Yes. 25 Q And that upset Johnson and Johnson very</p>

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<p>1 much, didn't it?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A I would say yes. They reacted to this</p> <p>4 because we know there was not asbestos in our</p> <p>5 talc.</p> <p>6 Q Johnson and Johnson 25 is a letter you</p> <p>7 sent back to Dr. Langer about the samples, right?</p> <p>8 A Yes. It appears to be.</p> <p>9 Q And you documented again that he said he</p> <p>10 found chrysotile asbestos, correct?</p> <p>11 A Could you highlight what you are referring</p> <p>12 to?</p> <p>13 Q Yes, Ma'am. You observed some chrysotile</p> <p>14 asbestos to be present in the tissue?</p> <p>15 A Yes. I see that.</p> <p>16 Q What you said to Dr. Langer was we don't</p> <p>17 think you should publish this material, correct?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A The essence of this letter appears more</p> <p>20 around the methods and what methods they used,</p> <p>21 trying to understand that.</p> <p>22 Q You state, "It suggests, therefore, that a</p> <p>23 publication of your observations are on potentially</p> <p>24 contaminated tissue may have limited scientific</p> <p>25 value."</p>	<p>1 A I don't recall that characterization.</p> <p>2 Q (J&J Exhibit-39). This is a November 29, 1972</p> <p>3 memo on Johnson and Johnson letterhead and it was to</p> <p>4 D.D. Johnston?</p> <p>5 A I see that.</p> <p>6 Q He was the president of the company at the</p> <p>7 time?</p> <p>8 A I didn't know that.</p> <p>9 Q The subject is Antagonistic Personalities</p> <p>10 in the Talc Story in the U.S., correct?</p> <p>11 A Yes.</p> <p>12 Q And one of those antagonistic</p> <p>13 personalities was at one time your friend, Dr.</p> <p>14 Selikoff, according to this memo, correct?</p> <p>15 A That's what it says, yes.</p> <p>16 Q And you state that, "The start of the</p> <p>17 attack on talc originated in England at the Tenovus</p> <p>18 Research Institute in Cardiff where a technician in</p> <p>19 microscopy published a paper." Right?</p> <p>20 A Yes. That's what it says.</p> <p>21 Q That was the institute that you were</p> <p>22 working with, collaborating with, and now they are the</p> <p>23 attackers?</p> <p>24 MR. SMITH: Objection.</p> <p>25 A This is the paper that we started with,</p>
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<p>1 A That's what it says, yes.</p> <p>2 Q So you had issues. Your position was,</p> <p>3 well, maybe you found asbestos, but it is possible</p> <p>4 the tissue was contaminated to begin with. That was</p> <p>5 your position, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A No. I think the question was around</p> <p>8 scientific methods, and we asked actually that the</p> <p>9 tumor sample be returned so that further study could</p> <p>10 be done.</p> <p>11 Q You wanted to get the samples back once he</p> <p>12 told you that he found asbestos, right?</p> <p>13 A No.</p> <p>14 Q You asked him for the samples back?</p> <p>15 A Correct.</p> <p>16 Q And then you paid him \$1000, right?</p> <p>17 A We paid him for the research he did, yes.</p> <p>18 That's correct.</p> <p>19 Q Now, you were aware that Dr. Selikoff also</p> <p>20 served as an adviser to the FDA?</p> <p>21 A I was not aware of that, no.</p> <p>22 Q After Dr. Selikoff found what he found, he</p> <p>23 was labeled by you not as a friend anymore, but as</p> <p>24 the attacker, correct?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 the Henderson Paper that they published independently</p> <p>2 and then we collaborated to follow up and try to</p> <p>3 understand what their findings were and engaged</p> <p>4 Dr. Selikoff to look at tissue. (Exhibit J&J-10)</p> <p>5 Q Right. The Institute, the Cancer</p> <p>6 Institute that you started cooperating with now was</p> <p>7 part of the attack on you, Johnson and Johnson,</p> <p>8 right?</p> <p>9 MR. SMITH: Objection.</p> <p>10 Q According to this.</p> <p>11 A It says attack on talc, not Johnson and</p> <p>12 Johnson.</p> <p>13 Q Then it says, "In the USA the leading</p> <p>14 group who initiated the attack on talc is located in</p> <p>15 New York City and consists of the following," and</p> <p>16 then you list Dr. Selikoff, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I see that.</p> <p>19 Q In the next page on paragraph 6 you talk</p> <p>20 about, "Although the FDA tries to be impartial in</p> <p>21 matters concerning drugs and health, there's a Dr.</p> <p>22 Weisler of the Department of the FDA concerned with</p> <p>23 food and cosmetics who is seeking recognition within</p> <p>24 the FDA. He has retained a consultant, Dr. Lewin,</p> <p>25 an analytical chemist of New York University for</p>

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<p>1 studying commercial talc products and their possible 2 asbestos content. Dr. Weisler seems particularly 3 anxious to condemn talc." Do you see that? 4 A I see that. 5 Q Dr. Weisler was the person who was working 6 at the FDA before your Dr. Ironman took his job, 7 correct? 8 A I don't know what the sequence of events 9 were there. 10 Q And Dr. Lewin was actually also a 11 scientist that was hired by members of your trade 12 institute, correct, before this time? 13 MR. SMITH: Objection. 14 A I believe he was hired by the FDA. I 15 don't recall that he worked for any organizations. 16 Q You didn't know he was hired by Whittaker, 17 Clark and Daniels who supplied you with talc? 18 MR. SMITH: Objection. 19 A I don't recall that, no. 20 Q So just to review for context, I think you 21 told us this last time, but just for context again, 22 what happened with Dr. Lewin was he was hired by the 23 FDA, and when he tested a whole host of talc, he 24 reported from his perspective that he had found 25 asbestos in Johnson's Baby Powder and Shower to</p>	<p>1 Q And the FDA agreed that they wouldn't let 2 the public see it until you had a chance to go over 3 it, correct? 4 A I don't believe that's exactly what they 5 said, but it is common when results come in for a 6 given product that a company manufacturers, that 7 those results would be sent to them right away for 8 comments, consideration, awareness. 9 Q I think you told me last time that you had 10 the relationship with the FDA. The FDA official 11 actually said this report will be released over my 12 dead body. Do you recall that? 13 MR. SMITH: Objection. 14 A I don't know what you mean we had a 15 relationship with them, and this comment that you 16 just made. I don't understand the connection. What 17 is the question? 18 Q The FDA promised Johnson and Johnson that 19 that the report would not be released over the FDA's 20 official "dead body?" 21 A That was an individual making a comment 22 from the FDA. I don't think that was a promise to 23 Johnson and Johnson. 24 Q So you didn't think it was a promise when 25 you wrote it down in a memo and said that you were</p>
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<p>1 Shower, correct? 2 A Yes. He reported numerous samples where 3 he found asbestos and later retracted those results. 4 Q We are going to get to that. 5 I think we discussed last time that 6 Johnson and Johnson actually received an advanced 7 report of the Lewin results before it was ever made 8 available to any member of Congress or any doctor, 9 correct? 10 A The FDA, yes, they did send us a copy of 11 the report before any other communications were 12 made. 13 Q Johnson and Johnson interceded with the 14 FDA and the FDA promised Johnson and Johnson it 15 would not release the Lewin report without Johnson 16 and Johnson's opportunity to review the report, 17 correct? 18 A I don't know what you mean by interceded. 19 Q You called them up and said please don't 20 release the report until we can look at it and give 21 our own comments, fair? 22 MR. SMITH: Objection. 23 A I don't think that's correct. I think we 24 said we would like to look at that report before you 25 share it.</p>	<p>1 told that it wouldn't be released, but over the 2 FDA's official dead body? You didn't consider that 3 a promise? 4 A No. That was a comment made by an 5 official at FDA. 6 Q Is it fair to say that Johnson and 7 Johnson disagreed with Dr. Lewin's findings? 8 A We did disagree and he later retracted 9 those results, as they were incorrect. 10 Q I'm just asking you whether you disagreed 11 with the original findings. 12 A Yes, we did. 13 Q And what happened was in order to respond 14 to Dr. Lewin's results, you hired a number of 15 experts to look at the same samples, correct? 16 A That is correct. 17 Q And those were the experts that are on 18 this chart that we went through this morning, 19 correct? 20 A That is correct. 21 Q And, in fact, what the chart reflects 22 mostly is the experts that you hired to look at the 23 Lewin samples and what they found, correct? 24 A The chart, yes. There were other -- the 25 FDA also hired an independent lab to look at those</p>

<p style="text-align: right;">Page 316</p> <p>1 samples.</p> <p>2 Q I'm going to get to that. I promise.</p> <p>3 One of the experts, I think we went</p> <p>4 through them on the chart, that you hired, you,</p> <p>5 Johnson and Johnson, to refute the Lewin results,</p> <p>6 was the McCrone Institute, correct?</p> <p>7 A That is correct.</p> <p>8 Q And I think you testified last time</p> <p>9 Johnson and Johnson told the FDA McCrone never found</p> <p>10 asbestos in any material used to make Johnson's Baby</p> <p>11 Powder, correct?</p> <p>12 A Production material, that is correct.</p> <p>13 Q And that McCrone never found any form of</p> <p>14 asbestos in the source of talc used in Johnson's</p> <p>15 Baby Powder, correct?</p> <p>16 A What do you mean, the source of talc?</p> <p>17 Q The mines that were used to make the baby</p> <p>18 powder.</p> <p>19 A In the ore that comes out of the mines?</p> <p>20 Q Yes, Ma'am.</p> <p>21 A That's correct. We didn't find any</p> <p>22 asbestos in the ore that was used to make baby</p> <p>23 powder.</p> <p>24 Q Do you have in front of you the report</p> <p>25 that McCrone did on -- I'm just talking about baby</p>	<p style="text-align: right;">Page 318</p> <p>1 Q And is this the first time you have seen</p> <p>2 this report?</p> <p>3 A I may have seen it before, but not in</p> <p>4 preparation for this deposition.</p> <p>5 Q And in this report on page 2 there's a</p> <p>6 summary, correct?</p> <p>7 A Yes.</p> <p>8 Q And it actually reports the amount of</p> <p>9 tremolite that was found by McCrone, correct?</p> <p>10 A Correct.</p> <p>11 Q When it talks about total tremolite</p> <p>12 contents on the last page, it talks about .5 percent</p> <p>13 per 108T and about .2 to .3 for 109T, correct?</p> <p>14 A Yes.</p> <p>15 Q That's Johnson's Baby Powder, correct?</p> <p>16 A Correct.</p> <p>17 Q And down at the bottom it says, "A few</p> <p>18 tremolite rods were observed in both samples at a</p> <p>19 level less than .5 percent. No chrysotile was</p> <p>20 detected," correct?</p> <p>21 A Yes.</p> <p>22 Q That information never made it into the</p> <p>23 report that you sent to the FDA, correct?</p> <p>24 A That is correct.</p> <p>25 Q And Exhibit 34 is another version of the</p>
<p style="text-align: right;">Page 317</p> <p>1 powder now. The report McCrone did on 10-27-72,</p> <p>2 25C? 25C is the 10-27-1972 report of McCrone</p> <p>3 concerning the examination of Johnson's Baby Powder,</p> <p>4 correct?</p> <p>5 A Correct.</p> <p>6 Q That's the report you gave to the FDA,</p> <p>7 correct?</p> <p>8 A In 1972, yes.</p> <p>9 Q Yes, Ma'am. And that report was the</p> <p>10 edited report. Can we agree on that?</p> <p>11 A I don't know that it is an edited report.</p> <p>12 Q You don't know that there were other</p> <p>13 versions of this report where the results were</p> <p>14 edited out and you gave a different report to the</p> <p>15 FDA? You never knew that?</p> <p>16 A I think every report undergoes editing.</p> <p>17 We have to look at that specifically to see exactly</p> <p>18 what you are referring to.</p> <p>19 Q Exhibit 36 is a report dated October 27,</p> <p>20 1972, examination of Johnson and Johnson Baby Powder</p> <p>21 by McCrone. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q And it says, "Do not use this report.</p> <p>24 Replaced by another version." Do you see that?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 319</p> <p>1 report. Have you seen this version before?</p> <p>2 A I don't recall that I have.</p> <p>3 Q Do you see in this version under summary</p> <p>4 they crossed out the amount and instead they write</p> <p>5 in a few isolated crystals. Do you see that?</p> <p>6 A Yes.</p> <p>7 Q And then on the last page under results</p> <p>8 the total tremolite content is crossed out entirely.</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q And then on the bottom the levels are</p> <p>12 crossed out, correct?</p> <p>13 A Correct.</p> <p>14 Q What I put up here, 479, just so the</p> <p>15 record is clear, shows the original of the</p> <p>16 information on light microscopy from the original</p> <p>17 report and the edited report. Do you see that?</p> <p>18 A Yes.</p> <p>19 Q Did you ever see this before?</p> <p>20 A Not this exact picture, no.</p> <p>21 Q The fact that there was tremolite in</p> <p>22 Johnson's Baby Powder, that was nothing new to</p> <p>23 Johnson and Johnson, right? Everybody in the</p> <p>24 company knew that already?</p> <p>25 MR. SMITH: Objection.</p>

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<p>1 A Tremolite is not asbestos. Yes, people 2 were aware there's tremolite in talc. 3 Q Ma'am, that wasn't my question. Let me 4 ask it and we will fight over whether tremolite is in 5 asbestos or not before a jury. 6 All I'm asking you now is it was not 7 new news. Everybody knew there was tremolite in 8 Johnson's Baby Powder, correct? 9 MR. SMITH: Objection. 10 A Not correct. Everyone -- every person 11 obviously wouldn't know, and tremolite is not always 12 found in talc. 13 Q In front of you is Exhibit 26, and if you 14 go to the second page of 26, do you see where it 15 says, "Revised report, just received?" and it gives 16 the lot numbers? 17 A That's not what you just handed me. 18 Q Turn it over. 19 A Got it. Sorry. 20 Q It says, "Revised report just received" 21 108T and 109T, correct? 22 A Yes. 23 Q That's the McCrone report, right? 24 A I have to look at the date. It says on 25 the front, McCrone.</p>	<p>1 you, Johnson and Johnson, were aware that those 2 samples may not even be representative of Johnson 3 and Johnson talc, correct? 4 MR. SMITH: Objection. 5 A No. 6 Q You, Johnson and Johnson, actually were 7 happy that the Lewin samples were sent out to the 8 FDA before you found actinolite in the Johnson and 9 Johnson Baby Powder, correct? 10 MR. SMITH: Objection. 11 A I don't know what you are referring to. 12 Q Did you know that Johnson and Johnson hid 13 from the FDA that they found actinolite in the talc 14 that was used to make baby powder right around the 15 same time that Lewin was doing all these tests? 16 MR. SMITH: Objection. 17 Q Did you know that? 18 A No. That sounds incorrect. 19 Q Okay. I'm trying to figure out why they 20 would do that. But let's see if we can figure that 21 out? 22 MR. SMITH: Objection. 23 Q 368. 368 is a memo from May 8, 1973, 24 entitled Personal, Dr. D. Petterson, the president of 25 the company, correct?</p>
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<p>1 Q Right. And who is Nashad? 2 A Nashad was a research and development 3 employee of Johnson and Johnson. 4 Q He wrote to Dr. Goudie. Who is Dr. 5 Goudie? 6 A I don't remember. Dr. Goudie is another 7 person at Johnson and Johnson. 8 Q He received a whole bunch of these tests 9 on this chart, right? 10 A Right. 11 Q And Nashad writes to Goudie, "I thought 12 tremolite was mistakenly identified in view of 13 similarity to..." and then it gives some name I can't 14 say. Can you say that name? 15 A Sesquictrate. 16 Q What he writes side back is, "There are 17 trace quantities present confirmed both by McCrone 18 and Bill Ashton." Correct? 19 A Yes. 20 Q This is not new, correct? 21 MR. SMITH: Objection. 22 A Yes. 23 Q Johnson and Johnson, when all this was 24 going on, and this testing was being done of the 25 Johnson Baby Powder samples, the Lewin samples,</p>	<p>1 A I don't know who was president at that 2 time. 3 Q It states that, "Your question this 4 morning was how did Lewin assay timing relate to 5 actinolite showings? Baby Powder lots 108T and 109T 6 were alleged to contain asbestiforms by Lewin. 7 They were produced on April 17 and 18, 1972. Talc 8 shipments checked by microscope here showed all lots 9 clean just prior to and right after that time." Do 10 you see that? 11 A Yes. 12 Q Then it says, "The first showing of 13 actinolite we know about is October 1972. The 14 indications are that things were in good shape when 15 Lewin picked up the above two lots for his assays." 16 Correct? 17 A That's what it says. 18 Q That was signed by W. A., William Ashton, 19 correct? 20 A Appears to be, yes. 21 Q So you never told the FDA, did you, that 22 while Dr. Lewin was running the tests, Johnson and 23 Johnson knew that there was actinolite in the source 24 of talc for its baby powder, correct? 25 A I didn't quite follow your question, but</p>

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<p>1 actinolite isn't asbestos and it was a conversation 2 about asbestos and baby powder. So I don't see the 3 relation of the two things.</p> <p>4 Q Ma'am, actinolite can be asbestos and it 5 cannot be asbestos. It depends on what the results 6 are, correct?</p> <p>7 A That is correct.</p> <p>8 Q And here it doesn't say whether it is 9 asbestos or not asbestos, correct?</p> <p>10 A It doesn't say it is asbestos. If it is 11 asbestos, you say actinolite asbestos.</p> <p>12 Q We are going to get to that.</p> <p>13 Here what is reported is that there 14 was actinolite in that the characterization by 15 Johnson and Johnson is we are in good shape because 16 that stuff never went to Dr. Lewin, right? That's 17 what the memo says?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A No. That is not what the memo says.</p> <p>20 Q Let's just read the memo for the record, 21 and somebody else will make that determination.</p> <p>22 It says, "The first showing of 23 actinolite we know about is October 1972. The 24 indications are that things were in good shape when 25 Lewin picked up the above two lots for his assays."</p>	<p>1 going to go to the end because I promised counsel we 2 are going to deal with some issues at the witness's 3 request?</p> <p>4 MR. SMITH: Yes.</p> <p>5 Q I wanted to shift focus for the remainder 6 of today to the Lewin tests related to Shower to 7 Shower. Okay?</p> <p>8 A Yes.</p> <p>9 Q I promise you I'm not done. I know you 10 have a lot more to tell us.</p> <p>11 What is G11? What is the ingredient 12 in G11 that you use in Shower to Shower? What is 13 that for?</p> <p>14 A I have no idea what that is.</p> <p>15 Q It is not a special designation for some 16 talc additive?</p> <p>17 A Not that I'm aware of. I don't know.</p> <p>18 Q You never heard the word G11 before?</p> <p>19 A Not that I recall, no.</p> <p>20 Q I think we went over this morning, but 21 to refresh, Johnson and Johnson cited the tests 22 that McCrone did to the FDA in support of its 23 position that there was no evidence of asbestos 24 in the Shower to Shower product, and that Dr. Lewin 25 was incorrect.</p>
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<p>1 That's what it says, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A That is what it says.</p> <p>4 Q Do you have any evidence, as you sit here 5 today, that Johnson and Johnson ever advised the FDA 6 that they knew there was actinolite in the Johnson's 7 Baby Powder?</p> <p>8 A No, because actinolite isn't asbestos.</p> <p>9 There would have been no reason to tell them that.</p> <p>10 Q Let me ask you the question again, please.</p> <p>11 As you sit here today, do you have any evidence to 12 indicate that Johnson and Johnson ever told the FDA 13 that they knew there was actinolite in Johnson's 14 Baby Powder? Yes or no?</p> <p>15 A No.</p> <p>16 MR. PLACITELLA: Let's take a break.</p> <p>17 THE VIDEOGRAPHER: The time is 2:48.</p> <p>18 We are going off the record. 19 (Recess taken)</p> <p>20</p> <p>21 THE VIDEOGRAPHER: The time is 22 approximately 3:02. We are now back on the video 23 record. Counsel, you may proceed.</p> <p>24</p> <p>25 MR. PLACITELLA: We are probably not</p>	<p>1 Is that fair?</p> <p>2 A I believe that's correct, yes.</p> <p>3 Q In the context of these cases, we sent 4 subpoenas out to McCrone for their records. Have 5 you looked at McCrone's internal records related to 6 the testing of the Shower to Shower product?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A I have not.</p> <p>9 Q 376, the second page is a draft of notes 10 that were produced by McCrone with the Bates number 11 from this case. Do you see it in the lower right 12 hand corner?</p> <p>13 A Yes.</p> <p>14 Q The date of this is 11-11-71. The draft 15 is to Dr. Goudie at Johnson and Johnson and it 16 relates to medicated powder and Shower to Shower. 17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q As it relates to Shower to Shower, there's 20 a section with a big X through it. Do you see that?</p> <p>21 A Yes.</p> <p>22 Q It says, "The Shower to Shower appeared to 23 have a few more fibers than the other two samples. 24 However, I think that might be due to possible 25 contamination from the G11. In the G11 we did find</p>

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<p>1 two positively identified chrysotile fibers and some 2 other fibers which, at first glance, appeared to be 3 chrysotile when you look at the electron diffraction 4 patterns. I believe that most of the fibers in the 5 Shower to Shower, which are suspect, may come from 6 G11."</p> <p>7 Did you ever see this before? 8 MR. SMITH: Objection.</p> <p>9 A No. 10 Q I guess this wasn't shared with you in 11 preparation for your deposition? 12 A No. This is a McCrone document. I 13 wouldn't have seen it. 14 Q Then it says on the bottom, this is from 15 McCrone now, "I left out the comments on G11 from 16 the report because I felt you might want to change 17 your supplier or investigate your supplier. And 18 this would only tend to, and then I guess there's a 19 line, perhaps confuse the issue with the FDA." Do 20 you see that? 21 A I do. 22 Q So, is this the first time you found out 23 that McCrone purposely kept information on 24 chrysotile findings in Shower to Shower from the 25 FDA?</p>	<p>1 A I don't know. I don't know what G11 is. 2 I really have no idea. 3 Q 485 are other handwritten notes that were 4 obtained from McCrone, and these notes are entitled 5 Transmission Electron Microscope, Hutchinson, 6 University of Minnesota. Do you see that? 7 A Yes. 8 Q Have you ever seen these notes before? 9 A No. 10 Q They were not shared with you in 11 preparation for your deposition? 12 A No. The scope of the deposition was 13 communications between us and the FDA. 14 Q The scope was what you knew about and gave 15 to the FDA and what you didn't give to the FDA. You 16 knew that, right? It wasn't just about what you 17 gave, it was about what you didn't give. 18 MR. SMITH: Objection. 19 A Communications related to asbestos testing 20 in our talc material. 21 Q Do you see under the section on Lewin? 22 A Yes. 23 Q It talks about the TEM test and it says, 24 "Five fibrous particles were found which gave 25 electron diffraction pattern unmistakably chrysotile</p>
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<p>1 MR. SMITH: Objection. 2 A I don't know what that is. I don't know 3 what G11 is. I can't comment on that. 4 Q Do you think it is proper to just edit 5 parts out of reports because you are afraid of what 6 the FDA may think? 7 MR. SMITH: Objection. 8 A No, and I'm not sure that's what this said 9 G11 could be a non production additive for a 10 product. I really don't know, so I wouldn't jump to 11 conclusions. 12 Q Did you change your supplier after that so 13 you could get the asbestos out of the Shower to 14 Shower like McCrone said you should? 15 A I don't know what G11 is. 16 MR. SMITH: Objection. 17 Q Who should we ask then? It is kind of 18 important. 19 MR. SMITH: Objection. 20 A I don't know what G11 is. McCrone did the 21 testing. Perhaps they have the answer. 22 Q Who at job Johnson and Johnson should we 23 ask about G11, and what it was that was kept from 24 the FDA about G11? Who should we ask? 25 MR. SMITH: Objection.</p>	<p>1 asbestos." Do you see that? 2 MR. SMITH: Objection. 3 A I do. 4 Q Is this the first time you found out that 5 McCrone had in its files handwritten notes related 6 to what the University of Minnesota did where they 7 found asbestos in Shower to Shower? 8 MR. SMITH: Objection. 9 A I don't think you can jump to that 10 conclusion from these notes. 11 Q You see under the next section Shower to 12 Shower? 13 A Yes. 14 Q And do you see where it talks about clear 15 samples found of serpentine material which gave 16 perfect chrysotile patterns? Do you see that? 17 A I do. 18 Q Was this information ever transmitted to 19 the FDA? 20 MR. SMITH: Objection. 21 Q About Shower to Shower? 22 A I don't know what these notes refer to. 23 If you will recall, there were a number of samples 24 where chrysotile was actually added to the samples 25 to look at the sensitivity of different testing</p>

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<p>1 methods. So I think you can't jump to conclusions 2 about what this lab book actually reflects in terms 3 of testing. 4 Q Ma'am, there's nothing in these notes 5 about adding. Take a look. See if there's anything 6 in there about adding chrysotile to Shower to Shower 7 in these notes. 8 A What I see is it transmission electron 9 microscopy samples and the method for sample 10 preparation are not included in these notes. We 11 couldn't know that. 12 Q There's nothing in these notes to indicate 13 that somehow somebody added asbestos and then said 14 oh, yes, we found asbestos, right? 15 MR. SMITH: Objection. 16 A The methods are not included in the notes 17 you gave me, so we have no idea what these samples 18 are. 19 Q Let's go to the last page where they talk 20 about Shower to Shower. It says, "Total 21 concentration calculation (Shower to Shower). 22 Prints of micrographs were cut to estimate the 23 relative area of asbestos and talc. On both one 24 square contained incontrovertible asbestos." Do you 25 see that?</p>	<p>1 MR. SMITH: Objection. 2 A Based on what you have given me, I don't 3 think this says they found asbestos in the samples. 4 You haven't provided the full document. 5 Q Ma'am, I provided the full document that 6 was given to us by McCrone. You have never been 7 provided this document before this very minute, 8 correct? 9 MR. SMITH: Objection. 10 A That is correct, but this document is 11 incomplete. I don't think you can jump to 12 conclusions based on this partial experimental 13 document. 14 Q This document was never shared with you 15 before this very minute, correct? 16 A That is correct, and it looks like a 17 partial document. There's important parts of this 18 that are missing. 19 Q You see at the bottom where it is actually 20 signed off on at the end of the document? 21 A Yes. When you do a lab book like this, 22 the pages are numbered. There are no numbers on 23 these pages. Is this two pages of ten or fifteen or 24 how many? It doesn't say. 25 Q The person who did the test signed off on</p>
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<p>1 MR. SMITH: Objection. 2 A That's what it looks like. 3 Q Anything in there about adding asbestos to 4 the baby powder? 5 A Again, you have not included the methods 6 for how these samples were prepared. You can't jump 7 to the conclusion you are jumping to. 8 Q I'm not concluding anything. I got this 9 document from McCrone. By the way, where are these 10 micrographs? That would tell us the story, wouldn't 11 it? 12 MR. SMITH: Objection. 13 A I've not seen these partial notes before 14 and the micrographs aren't included, nor the methods 15 included in what you gave me. 16 Q Well, where are the micrographs? 17 MR. SMITH: Objection. 18 A You provided me. I would ask you where 19 the micrographs and the information about how these 20 examples were prepared. 21 Q If you get a test result that finds 22 asbestos in your baby powder, wouldn't you save the 23 samples and the micrographs? 24 MR. SMITH: Objection. 25 Q Wouldn't that be normal procedure?</p>	<p>1 the test at the end, correct? That's the signature? 2 A I don't know this is the end. You don't 3 know if this is page nine of ten or where are the 4 other pages? 5 Q Why don't we do this because we are not 6 going to finish this time. Why don't you go back 7 and find it and tell me where the rest are, okay? 8 MR. SMITH: Objection. 9 A This is not a J & J document. It is from 10 McCrone. We wouldn't have the source documents. 11 Q They worked for you. Why wouldn't they 12 give you the source documents? 13 MR. SMITH: Objection. 14 A You provided the document. 15 Q Well, you know that the University of 16 Minnesota took this document, this base document and 17 turned it into a formal report that they gave to 18 you, right? 19 MR. SMITH: Objection. 20 Q You know that, right? 21 A No, I don't know that. I haven't seen 22 that report. 23 Q Ma'am, as you sit here today in preparing 24 for today's deposition, about what was given and not 25 given to the FDA, you have no idea that the</p>

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<p>1 University of Minnesota did a full report on what 2 they found in Johnson's Baby Powder? 3 MR. SMITH: Objection. 4 A I don't recall seeing a report from the 5 University of Minnesota. 6 Q Exhibit 33 is a report from the University 7 of Minnesota Space Science Center. Have you ever 8 seen this before? 9 A I might need a minute to look at. 10 Q Please take your time. 11 A It doesn't look familiar. 12 Q Please take your time. 13 A I may have seen this. I didn't review it 14 in preparation for the deposition today. 15 Q Go to the first page. It is entitled 16 Investigation of Possible Asbestos Contamination in 17 Talc Samples. Do you see that? 18 A Yes. 19 Q It says, "Specimens of powdered talc were 20 received from Johnson and Johnson Company and 21 McCrone Associates." Do you see that? 22 A Yes, I do. 23 Q "Analysis of these samples using the 24 scanning electron microscope was requested in order 25 to determine possible content of fibrous chrysotile</p>	<p>1 asbestos in the Shower to Shower material and one 2 example was found in the Lewin material." Correct? 3 A Yes. 4 Q So he was apparently looking at both the 5 Lewin material and the material you, Johnson and 6 Johnson, gave them of Shower to Shower, correct? 7 A Yes. 8 Q And what he says on the very next page is, 9 "In figures 17 and 18, electron micrographs of the 10 transmission type show the typical stranded 11 appearance of chrysotile asbestos." Correct? 12 A Yes. I see that. 13 Q He goes on to state, "It is felt, 14 therefore, that chrysotile asbestos does exist in 15 the specimens of Shower to Shower and Lewin supplied 16 to this laboratory." Correct? 17 A Yes. 18 Q Then what he attaches are the actual 19 pictures of the photo micrographs that were 20 referenced in the notes that we just went through, 21 correct? 22 A I cannot make a connection between the 23 document you gave me and these figures. I don't 24 know that it refers to the same experiment. 25 Q Do you have any evidence as you sit here</p>
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<p>1 asbestos contaminated in the talc samples." Do you 2 see that? 3 A Yes, I do. 4 Q Do you see on the next page where they 5 talk about that they are looking at the Lewin Shower 6 to Shower materials? 7 MR. SMITH: Objection. 8 A Yes. 9 Q Do you see on page 3 they have the results 10 of what they did with the transmission electron 11 microscope? Do you see that? 12 A Yes, I do see that. 13 Q And the transmission electron microscope 14 is the microscope that Johnson and Johnson said was 15 the gold standard for finding asbestos in talc, 16 correct? 17 A Yes. 18 Q And what the author says here is that he 19 looked at a large number of grids and found numerous 20 examples of fibrous material. Correct? 21 A Yes. 22 Q He goes on to say, "Of the large number of 23 grids examined, three examples of fibers, which upon 24 examination by electron diffraction, could be 25 classified as likely candidates for chrysotile</p>	<p>1 today that you ever provided a copy of this report 2 to the Food and Drug Administration? 3 A I don't know that we did. I do see that 4 it looks like the purpose of this report had to do 5 with scanning electron microscopy versus x-ray 6 dispersion, versus transmission electron microscopy, 7 and I would have to look through the material to see 8 if this is referenced in some way during the 9 discussions of methods developed. 10 Q Respectfully I move to strike your answer. 11 My question was, do you have any 12 evidence, as you sit here today, that a full copy of 13 this report was ever provided to the FDA? 14 A That's a different question. 15 Q Yes, Ma'am. 16 A A full copy of this report, no, or I would 17 have seen it. Was the information transmitted in 18 some other context that I'm not aware of, no, I 19 can't answer. 20 Q You do know that what happened was that 21 McCrone, when they submitted their report to the FDA 22 that you did give to the FDA, took edited pieces of 23 this report, selected pieces to suit its needs, 24 right? That's what happened. 25 MR. SMITH: Objection.</p>

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<p>1 A I don't know that's what happened, no.</p> <p>2 Q You have tab 36. Tab 36 is the report</p> <p>3 from McCrone dated June 22, 1973 related to Shower</p> <p>4 to Shower. Do you have that in front of you?</p> <p>5 A My tab 36 is a letter to Dr. Schaffner at</p> <p>6 the FDA. In here there's a report. Let me dig</p> <p>7 through here.</p> <p>8 Q The letter attaches the McCrone report.</p> <p>9 A I'm looking here. There are several</p> <p>10 reports. I got it.</p> <p>11 Q And this is the report that McCrone and</p> <p>12 Johnson and Johnson told the FDA that an extensive</p> <p>13 examination of the samples found no asbestos,</p> <p>14 including TEM, correct, and no chrysotile, right?</p> <p>15 A That is what it says.</p> <p>16 Q And if I go to page 6 of the report, you</p> <p>17 actually quote from the Hutchinson report, right?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A Yes, I see that.</p> <p>20 Q Are you with me now?</p> <p>21 A I am.</p> <p>22 Q And the Hutchinson report, you take to the</p> <p>23 FDA and you actually quote from J & J 33, correct?</p> <p>24 A Yes.</p> <p>25 Q And you start out quoting the conclusion</p>	<p>1 those documents.</p> <p>2 Q You are referring to 49, and I want to put</p> <p>3 that up. This is what you were referring to, where</p> <p>4 it says original?</p> <p>5 A Yes.</p> <p>6 Q The part I'm assuming that you are</p> <p>7 referring to is the very end which talks about</p> <p>8 chlorite?</p> <p>9 A Yes.</p> <p>10 Q Do you see here that's not talking about</p> <p>11 the Lewin report, right? That's talking about a</p> <p>12 sample and the batch number 1501Z, correct?</p> <p>13 A I'm trying to cross reference the various</p> <p>14 things here and again, I'm not an expert in chlorite</p> <p>15 versus asbestos and chrysotile, so I'm doing my best</p> <p>16 to cross manage.</p> <p>17 Q That's not the issue, Ma'am. When it</p> <p>18 talks about chlorite, it is referring to a specific</p> <p>19 example, 1501Z, correct, not the Lewin samples,</p> <p>20 correct?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A I don't know that that's not a Lewin</p> <p>23 sample. That's what I'm trying to figure out.</p> <p>24 Q Ma'am, that same statement is in the</p> <p>25 report that you gave to the FDA. That is nothing</p>
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<p>1 from the report. It says, "The extensive</p> <p>2 investigation reported here must conclude," right?</p> <p>3 A Yes.</p> <p>4 Q You have ellipses in your report, right,</p> <p>5 meaning stuff taken out?</p> <p>6 A Yes.</p> <p>7 Q And the stuff you took out was about</p> <p>8 Hutchinson's findings of asbestos, right.</p> <p>9 A Yes.</p> <p>10 MR. SMITH: Objection.</p> <p>11 A You hand me another document which refers</p> <p>12 to those results and it says that the original</p> <p>13 reports of chrysotile were erroneous and a</p> <p>14 misidentification of chlorite. Perhaps that's why</p> <p>15 they took that out of the report.</p> <p>16 Q What you did is, and we are going to get</p> <p>17 to that, what you did is, and that's why I handed it</p> <p>18 to you so we would have the whole truth here, is</p> <p>19 that you didn't give the FDA the report. You edited</p> <p>20 out the parts about asbestos, right? That's what</p> <p>21 you did?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A No. From what you just handed me it looks</p> <p>24 like those were incorrect results and those were</p> <p>25 chlorite. I haven't had a chance to review all</p>	<p>1 new, right?</p> <p>2 MR. SMITH: Objection.</p> <p>3 Q That conclusion is what you gave to the</p> <p>4 FDA?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A Yes.</p> <p>7 Q What you didn't give to the FDA, and what</p> <p>8 you edited out of the report you gave to the FDA</p> <p>9 were the findings by Hutchinson of chrysotile</p> <p>10 asbestos in your baby powder, correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 Q You didn't give that.</p> <p>13 MR. SMITH: Objection.</p> <p>14 A No, we didn't because in this document you</p> <p>15 just gave me, and I did find 1501Z. This is listed</p> <p>16 in the samples. It is the same batch as Lewin that</p> <p>17 there was mistakenly, and I'm not a microscopist,</p> <p>18 that they mistook chlorite for chrysotile.</p> <p>19 Q So it was the Lewin sample they made the</p> <p>20 mistake in? Is that your testimony?</p> <p>21 A Again, I'm not expert microscopist. I'm</p> <p>22 reading the document you put in front me. Page 3</p> <p>23 describes all the samples. 1501Z is the same sample</p> <p>24 batch that was examined by Professor Lewin. That's</p> <p>25 what it says.</p>

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<p>1 Q So when we go back to the Hutchinson 2 report, and it talks about looking at numerous 3 samples they talk about finding chrysotile in Shower 4 to Shower that was provided by both Lewin and 5 Johnson and Johnson, right? 6 MR. SMITH: Objection. 7 A Yes. 8 Q And nowhere did you disclose that 9 Hutchinson found chrysotile asbestos in the samples 10 you gave them that weren't Lewin samples, correct? 11 MR. SMITH: Objection. 12 A No. Not according to the document you 13 just gave me that says they mistakenly thought 14 chlorite was chrysotile. 15 Q Ma'am, you told me that was in the Lewin 16 sample. I'm asking you, you never told the FDA that 17 you have gave University of Minnesota other Shower 18 to Shower samples where they found chrysotile 19 asbestos. You never told them that, correct? 20 A Well, I don't know that that's true as I 21 haven't had the opportunity to cross check these 22 different documents on which samples they are 23 referring to. And again, this was a time when 24 people are making a lot of mistakes in 25 interpretation due to the lack of knowledge of</p>	<p>1 MR. SMITH: Objection. 2 A That's correct, because it appears they 3 had mistakenly identified chlorite as chrysotile. 4 Q In the handwritten notes -- scratch that. 5 J & J 58, have you seen this document 6 before, J & J 58? 7 A I may have. 8 Q What is your knowledge of J & J 58? 9 A I don't recall all the specifics, but I 10 see right up front there's the quantifying 11 asbestiform amphiboles in talc products. There was 12 some controversy over the methods used in grain 13 counting versus volume counting. 14 Q Can you tell me whether in J & J 58 it 15 talks about the purpose of the study dealing with 16 the concentration method? We did the last time, 17 correct? Do you remember we went through this? 18 A It may be two different things. The 19 concentration method versus concentration of 20 asbestos in talc materials. I think those are two 21 different concepts. 22 Q Do you recall we did this last time? I 23 don't really want to do this all over again. 24 Let me ask you this maybe I can 25 shortcut it. Do you have any record of this study</p>
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<p>1 methodology. 2 Q Ma'am, I respectfully move to strike that. 3 You never told the FDA that you gave 4 University of Minnesota samples of Shower to Shower 5 that weren't the Lewin samples where they found 6 chrysotile asbestos, correct? 7 A It appears so because that was not 8 chrysotile, it was chlorite, according to the 9 document you just showed me. 10 Q Move to strike, Ma'am. 11 When you sent the report to the FDA, 12 quoting Hutchinson, what you edited out was any 13 reference to asbestos, correct? 14 MR. SMITH: Objection. 15 Q That's what you did. 16 A That was left out of the report, yes. 17 Q And when you look at 478, I put side by 18 side, what you told the FDA on the top and what you 19 edited out on the bottom. Do you see that? 20 MR. SMITH: Objection. 21 A Yes. 22 Q What you edited out was transmission 23 electron microscopy showing less than one 24 hundreds of one percent asbestos in the material 25 given to us. That is what you edited out, correct?</p>	<p>1 done by Dartmouth ever being transmitted to the FDA? 2 A I don't think so. 3 Q I'm going to hand to you what's been 4 marked Musco-2. Do you know who Nancy Musco is? 5 A No. 6 Q Did you know she was somebody who 7 testified on behalf of Johnson and Johnson? 8 A No. 9 Q In this case? I'm going to show you 10 what's been marked Musco-2. You probably have to 11 move that. 12 MR. SMITH: Maybe I could see the 13 exhibit before you show it to the witness. 14 MR. PLACITELLA: Absolutely I'll do 15 that. No problem. 16 MR. SMITH: This is from the Musco 17 deposition? 18 MR. PLACITELLA: And others. 19 Off the video. 20 21 THE VIDEOGRAPHER: The time is 3:41. 22 We are going off the video. 23 THE VIDEOGRAPHER: The time is 3:45. 24 We are back on the video record. 25</p>

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<p>1 Q So you have in front of you first J & J 2 414. Do you see that? 3 A Yes. 4 Q I'll represent to you 414 was a chart that 5 was created, just like the chart we did today, at 6 the deposition of Dr. Hopkins. It took three days. 7 Have you had ever seen this chart before? 8 A No. 9 Q What we did is you can see the same exact 10 format. We went through all of the tests that were 11 produced and put the date, the exhibit number, the 12 testing entity, the author, the recipient, the 13 purpose, just like we did today. Do you see that? 14 A Yes. 15 Q For example, if you look at the entry for 16 3-9-71, for McCrone for Shower to Shower, it is the 17 same information we put on your chart. Do you see 18 that? 19 A Yes. 20 Q Just so I'm clear, no one ever shared this 21 chart with you before today? 22 A No. 23 Q And what you have is Musco-2 in front of 24 you? 25 A Yes.</p>	<p>1 the results, and I think there are a couple, you can 2 flip through it quickly, if you have any evidence 3 that you gave any of those results to the FDA at any 4 point in time? 5 MR. SMITH: Objection. 6 Q We can go off the video and you can take a 7 minute and we will figure out your other issue, 8 okay? 9 A I can't do this today. There are 370 10 documents here that I would have to look at and 11 cross reference them with other documents. 12 Q I promise that there's not 370. 13 A There are hundred 370 tabs. 14 Q There aren't. There are marks by exhibit 15 number. 16 A Missing numbers, missing tabs. 17 Q Just like before. 18 A I don't believe I can accurately answer 19 your question. 20 Q We know what you did provide. So all I 21 want to do is verify that you are didn't provide 22 anything that's in that book with one or two 23 exception. That's all and we will be done for the 24 today. 25 MR. SMITH: Objection.</p>
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<p>1 Q All the testing results that correspond to 2 that chart. If you want to look at it you can 3 verify the test. 4 A I see a big stack of paper here. I can't 5 verify that the chart is right. 6 Q Can you tell me from looking at Musco-2, 7 and we can take time and go off the video if you 8 want, which of the test results that are in Musco-2 9 Johnson and Johnson supplied to the FDA? 10 A Right off the top of my head I can't do 11 that, but I could provide context for why we sent 12 what we did send to the FDA. 13 Q All I want to know, Ma'am, we already did 14 that part. I want to know is in the book, Musco-2, 15 which are all the tests results we went over with 16 Dr. Hopkins, who you spoke to, correct? 17 A I have spoken to Dr. Hopkins, yes. 18 Q All the tests results we went over with 19 Dr. Hopkins, which of the test results that are in 20 Musco-2 did you provide to the FDA? That's all I 21 want to know. 22 A The results that we reviewed are on the 23 other table are the results that we supplied to the 24 FDA. 25 Q I want to just verify, Ma'am, if any of</p>	<p>1 A I'm not confident I can answer that 2 question accurately. 3 Q Let's put it this way. Anything in that 4 book that's after 1973 you didn't provide, right? 5 A That is correct. 6 Q So why don't you focus on the documents 7 for 1973 and before and tell me which ones you 8 provided. 9 A You want my opinion on why we wouldn't 10 wouldn't have provided these? 11 Q No, Ma'am. All I want to know is I just 12 am trying to get on the same page of what you gave 13 and what you didn't give. That is all I want do do 14 today. 15 MR. SMITH: If I might make a 16 proposal? 17 MR. PLACITELLA: To do what? 18 MR. SMITH: You got eight minutes 19 before we have got to get out of here. 20 MR. PLACITELLA: No, we have to get 21 out of here by 4:14. I promised I'll deal with your 22 issue. I would really like to get this on the 23 record before. 24 MR. SMITH: I thought you said you 25 wanted to be out of here by four o'clock.</p>

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<p>1 MR. PLACITELLA: I wanted to end by 2 four so I could deal with your issue. 3 MR. SMITH: I got you on that. To 4 end by four, we have eight minutes. 5 MR. PLACITELLA: Let's do our best. 6 The only thing she has to look at are documents 7 before 1973. Everything else, according to her 8 testimony, they never gave to the FDA. 9 MR. SMITH: I'm offering, and she is 10 going to come back. We know that. I could have her 11 look at this between now and then. If you want her 12 her to do it now, then you pick. 13 MR. PLACITELLA: I would like to 14 finish the record today. 15 MR. SMITH: I'm not sure you can. 16 MR. PLACITELLA: For this issue. 17 A Just in tab 9 there are multiple documents 18 in this tab, so I would have to turn page by page to 19 see what's actually here. 20 Q Okay. So I'll take your counsel's 21 suggestion so as to not labor and make you do this 22 here and now. 23 Is it fair to say, to close the 24 record for today, that if there's a test in there 25 that post dates 1973, based on the evidence you have</p>	<p>1 conversation outside how you want to deal with the 2 other issue. 3 THE VIDEOGRAPHER: The time is 4 approximately 3:54. This concludes today's video 5 deposition we are off the video record. 6 (The deposition is adjourned at 3:54 p.m.) 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 before you, it was never provided to the FDA? 2 A Not under the umbrella of asbestos testing 3 of our talc products, no. 4 Q Now, is it a fair question to ask you 5 which of the test results in there you ever saw 6 before today? 7 A I would have to flip through the pages and 8 really look at it. 9 Q Is it fair to say that if the documents 10 are not on the chart, your chart from this morning, 11 which I'm going to mark right now, you didn't 12 provide them to the FDA? 13 A As far as I know, no, we didn't. 14 MR. PLACITELLA: What I want to do 15 now is I want to mark this collectively as P-6. 16 (The above document is marked 17 P-6.) 18 Q P-6 is the chart that we created this 19 morning, correct? 20 A It appears to be, yes. 21 Q And that's true and accurate, to the best 22 of your knowledge? 23 A At this moment as best as I can do, yes. 24 MR. PLACITELLA: Why don't we close 25 the record for today on that and let's have a</p>	<p>1 CERTIFICATE 2 3 I, MARC BRODY, Notary Public and 4 Certified Shorthand Reporter of the State 5 of New Jersey, do hereby certify that prior 6 to the commencement of the examination 7 the witness was duly sworn by me to 8 testify the truth, the whole truth and 9 nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a true and accurate transcript 12 of the testimony as taken stenographically 13 by and before me at the time, place and on 14 the date hereinbefore set forth. 15 I DO FURTHER CERTIFY that I am neither 16 a relative of nor employee nor attorney nor 17 counsel for any of the parties to this 18 action, and that I am neither a relative 19 nor employee of such attorney or counsel, 20 and that I am not financially interested in 21 the action. 22 23 24 Notary Public of the State of New Jersey 25</p>

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2	NO. DESCRIPTION PAGE	
3	J&J-17 Meeting with Dr. Langer on	
4	July 9, Concerning Analytical	
5	Analysis of Talc 301	
6	J&J-24 Letter, Langer to Smith,	
7	11/10/71 307	
8	J&J-25 Letter, Smith to Langer, 12/14/71	308
9	J&J-39 Memo, Smith to Johnston, 11/29/72	310
10	J&J-10 Talc and Carcinoma of the Ovary	
11	And Cervix, W.J. Henderson, 3/71	311
12	J&J-36 Report, McCrone to Goudie,	
13	10/27/72, "DO NOT USE THIS REPORT"	317
14	J&J-34 Report, McCrone to Goudie,	
15	10/27/72 318	
16	J&J-479 Original/Altered Report:	
17	Light Microscopy 319	
18	J&J-26 Memo, Nashed to Goudie, 2 pp.	320
19	J&J-368 Memo, Ashton to Petterson, 5/8/73	322
20	J&J-376 Letter, McCrone to Goudie,	
21	10/12/71 327	
22	J&J-485 Handwritten Notes, Thomas	
23	Hutchinson, Univ. of Minnesota	330
24	J&J-33 Univ. Of Minnesota, Space Science	
25	Center, Investigation of Possible	
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3	J&J-49 Letter, McCrone to Goudie, 6/21/73	342
4	J&J-478 McCrone Manipulation of Hutchinson's	
5	Asbestos Results 345	
6	J&J-58 Memo, Confidential, Dartmouth	
7	College to Windsor Minerals, Inc.,	
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Exhibit 130

FDA-J&J Meeting
7/20/71

July 21, 1971

Special Talc Project No. 503
FDA Meeting, July 20, 1971

Dr. R. A. Fuller

Attendance:

FDA: Dr. R. Schaffner, Director, Office of Product Technology
Dr. L. Beacham, Dep. Dir., Office of Product Technology
Dr. A. Weissler, Director, Div. of Colors and Cosmetics
Technology
Dr. J. Gowdy (M.D.), Div. of Colors and Cosmetics
Technology
Dr. Eisenberg (microscopist)

J&J: Dr. G. Hildick-Smith, Dr. W. Nashed.

We reviewed briefly our official submission of July 20, 1971 (see attached letter). Dr. Schaffner signed our house copy acknowledging receipt.

We informed the group that, in addition to the work done by Colorado School of Mines Research Institute which showed that Baby Powder contains no asbestos, we have had Professor Pooley and the McCrone Associates and Johnson & Johnson laboratories do extensive examination of our talc and Baby Powder by electron microscopy. The results show that we have no asbestos in our product.

Dr. Weissler wanted to know if tremolite or fibrous talc was found. We stated that our information is that no asbestos was found and that we will have full detailed reports on the findings in about a week.

Dr. Hildick-Smith pointed out that Dr. William Smith's extensive work (10 years) under a PHS grant showed that tremolite talc did not produce tumors in animals while asbestos did. The information was included in our Exhibit 4.

Dr. Schaffner asked if we had been in touch with Dr. Selikoff to resolve the difference between his findings and ours. We said we plan to do so as soon as the reports of completed work is available.

Dr. R. A. Fuller

- 2 -

July 21, 1971

Dr. Schaffner said that his main mission at this time is to determine optimum methodology for examining talc samples. He asked Dr. Weissler to review his progress in this area. Dr. Weissler said that he had called Dr. Selikoff's office but that Dr. Selikoff was unavailable. He had also had the same experience in trying to contact Dr. Cralley (PHS Service, Cincinnati).

Dr. Gowdy raised the question of inhalation of fine particles of talc below 5 μ . He also said that there are cosmetic aerosol body powders and Dr. Schaffner asked for our particle size analysis of Baby Powder. We pointed out that our previous submission included particle size (by volume) analysis done by Colorado School of Mines and that we are currently preparing another report on particle size (in microns) of Baby Powder which would be submitted next week.

With regard to inhalation of fine inorganic particles, I pointed out that a farmer inhales a great deal of clay dust in his field throughout his life with no apparent danger and commented that if somebody was marketing clay Mr. Kretchmer would be asking FDA to ban it. This elicited amused smiles.

Dr. Eisenberg reviewed quickly the method supplied by Colorado School of Mines (Exhibit 2). He commented that he felt that the standard method followed by Colorado School of Mines using area % is a more valid procedure than electron microscopy.

Dr. Schaffner asked Dr. Weissler to set up a meeting, possibly Thursday of next week, with Dr. Selikoff and Dr. Cralley; also with our experts (Dr. Pooley, if available; Dr. McCrone; Mr. Caneer; and Dr. Rolle). He indicated that he has to give Dr. Edwards some recommendations in two weeks.

I told Dr. Schaffner that according to our previous discussion, we are supplying all our information to him and that he will coordinate dissemination of the information within the FDA. He agreed and said that they will also invite people from the Bureaus of Drugs and Product Safety to the discussion meeting to be set up by Dr. Weissler.

Finally, I stated that we have been doing a great deal of work without knowing precisely what Mr. Kretchmer's objections to talc were and that we can better direct our efforts if we know his specific objections. After some hesitation, Dr. Schaffner gave me a copy of Mr. Kretchmer's letter to the Secretary and a copy of the Kretchmer press release (see attached) and obtained my signature as a receipt on his copy.

Dr. R. A. Fuller

- 3 -

July 21, 1971

Actions:

We will provide FDA with:

1. Reports by Dr. Pooley, Dr. McCrone, and Johnson & Johnson on the results of electron microscopy examination of Baby Powder.
2. Report on particle size in microns of Baby Powder.
3. Convene our experts to meet with FDA at a date to be conveyed to us by Dr. Weissler.

W. Nashed

WN/cw

Attach.

cc: Mr. J. E. Burke
Mr. L. Foster
Dr. G. Hildick-Smith
Dr. T. H. Shelley
Mr. S. C. Smoyer
Mr. H. G. Stolzer to Mr. D. Clare
Mr. J. C. Walcott

Exhibit 131

J&J-FDA
9/21/71



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Johnson & Johnson

NEW BRUNSWICK, N. J.

September 21, 1971

R. Schaffner, Ph.D.
Director, Office of Product Technology
Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
200 "C" Street
Washington, D. C.

Subject: JOHNSON'S Baby Powder

Dear Dr. Schaffner:

My colleagues and I wish to express our thanks for your providing us the opportunity on August 3, 1971 to present our data and methods of testing of JOHNSON'S Baby Powder and the talc used in its manufacture.

As we discussed, we are submitting herewith full reports of our investigations as follows:

Identification of Samples used in the Pooley report and McCrone report.	Exhibit 1 [Vol. 1]
Letter from Colorado School of Mines Research Institute.	Exhibit 2 [Vol. 1]
Report by Johnson & Johnson Pharmaceutical Research Section: "Particle Size of JOHNSON'S Baby Powder."	Exhibit 3 [Vol. 1]
Report by Dr. F. D. Pooley, University College, Cardiff, Wales: "Report of Investigations of Talc Samples supplied by Johnson & Johnson."	Exhibit 4 [Vol. 1]
Reports by Walter C. McCrone Associates, Inc.:	Exhibit 5 [Vol. 2 - Vol. 3]
(a) "Methodology for the Determination of Asbestos in Talc."	
(b) "Examination of Baby Powder for Johnson & Johnson."	

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R. Schaffner, Ph.D.

- 2 -

September 21, 1971

It is seen that the data conclusively proves that JOHNSON'S Baby Powder is free of asbestos.

It is suggested in the interest of future references to this data that our filings of July 8 and July 20, 1971 as well as this filing be incorporated in a master file with a reference number which can be utilized in future communications on this matter.

Should you have any questions regarding the data submitted, we will be very pleased to answer them.

Thanks for your consideration.

Very truly yours,
JOHNSON & JOHNSON

W. Nashed

by: W. Nashed, Ph.D.
Director of Science Information

WN/cw

Attach: Vols. 1, 2, and 3

bcc: Mr. J. E. Burke
Mr. D. Clare
Dr. R. A. Fuller
Mr. L. Foster
Dr. G. Hildick-Smith
Dr. T. H. Shelley
Mr. S. C. Smoyer
Mr. J.C. Walcott

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The information and data submitted herein contains trade secrets, commercial or financial information or privileged or confidential information, and the Food and Drug Administration is not authorized to make them public without written permission from the company.

Exhibit 132

Johnson & Johnson

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

Dr. N. F. Estrin
C.T.F.A.

-2-

March 15, 1976

March 15, 1976

Dr. Norman F. Estrin
Vice President - Science
Cosmetic, Toiletries, and
Fragrance Association
1133 15th Street, N.W.
Washington, D.C. 20005

Re: Examination for Asbestos In Talc

Dear Dr. Estrin:

The talc which is used by Johnson & Johnson is solely derived from its own mine in Vermont, where the ore is mined selectively and then beneficiated by the process of flotation.

Shipments of this highly purified talc are routinely examined by our own laboratory to verify the absence of asbestos minerals.

Historically, Johnson & Johnson has always been concerned about the mineralogical integrity of its talcs and even its earliest specifications have required the examination for acicular particulates. When it was erroneously reported in 1971 that our powder contained asbestos, we sponsored a scientific seminar of mineralogical and analytical experts for the FDA to prove that our talc is not contaminated with asbestos. At that time numerous samples were analyzed by experienced consultants such as McCrone Associates, Colorado School of Mines, Professor F. D. Pooley (of the University College, Cardiff), Professor G. Brown (of Princeton), and Professor M. Buerger (of M.I.T.). These examinations included X-ray diffraction analysis, differential thermal analysis, and transmission electron microscopy.

During the period December 1972 to October 1973, 93 lots were individually sampled and examined by X-ray diffractometry for the presence of asbestos minerals. No amphiboles or serpentine minerals were detected in any sample.

Beginning in October 1973, differential thermal analysis was added to our specified requirement. Both, differential thermal analysis and X-ray diffractometry were instituted for the routine examination of sequential lots. A further 100 lots have since been examined, applying both methods to each sample. Again, no amphibole or serpentine minerals have been detected.

I would like to advise that we are continuing to employ differential thermal analysis and X-ray diffractometry in the examination of sequential lots for the detection of amphibole and serpentine minerals.

It should be pointed out that we also maintain a worldwide monitoring of talcs used by our Johnson & Johnson affiliates, employing these same techniques.

Finally, let me add that periodically, we also submit sub-samples for Transmission Electron Microscope examination and these have always verified the absence of asbestiform minerals.

It is our understanding that you would wish to submit this information to the FDA. Please regard this letter as non-confidential.

Sincerely yours,

George Lee
Director of Applied Research

GL/mm

WCDD000009.

Exhibit 133

JNJ000268964

Metadata

Confidentiality	Y	ORIGINAL
Custodian	Legacy 1	ORIGINAL
DocumentType	Physical	ORIGINAL

Dr. W. Nashed
Dr. T. H. Shelley
Dr. G. Hildick-Smith

Johnson & Johnson

1503
New Brunswick, N.J.
December 13, 1972

Subject: Meeting November 1, 1972
with Dr. Schaffner - F. D. A.

Talc File:

I met with Dr. Schaffner on November 1 and we had a frank, friendly talk for approximately an hour. I explained my mission and the necessity to make clear the concern of Johnson & Johnson management with respect to Dr. Lewin's report. I explained that from the beginning our company's attitude and actions had been to share information with the FDA in order to prevent unnecessary panic and irrational actions due to any ill-informed consumer pressures. We had, I pointed out, provided information and offered our complete background files to the administration prior to the public disclosures in this country of any concerns about talc per se or the potential contamination of talc with asbestos.

I pointed out that having listened to Dr. Lewin and to the presentations of the world authorities we had assembled as consultants, I was convinced that there wasn't a shred of evidence to support the idea that either our Johnson* Baby Powder or Shower to Shower* contained any chrysotile asbestos. I said it was therefore difficult for me to explain to my colleagues in Johnson & Johnson management why it had not been decided not to publish Dr. Lewin's report. I then concluded that unless he could assure me that the report would not be issued I was instructed to make an appointment with Commissioner Edwards and make our viewpoint known to him. We felt this was necessary to be assured that the seriousness with which we view this situation and its potential effect on our business was known at all levels of the administration so that it could be viewed in the light of any consumer pressures.

Dr. Schaffner did not disagree with me and repeated that he had not seen the report on our Baby Powder samples which had obviously irritated him. He agreed that we had indeed assembled competent people and appeared sympathetic to our views. He asked how much we had spent and I gave him a reasonable estimate. He told me confidentially and asked that I not publicize it, that he had received a comment from an optical microscopist on the FDA staff in a discussion of another problem, that Dr. Lewin was wrong and that he was "outside his field of competence". I confirmed that that was our view and that of our consultants. He went on to say that he had asked the Bureau of Mines "as suggested

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Meeting November 1, 1972
with Dr. Schaffner - FDA

December 13, 1972

by Dr. Nashed" to review this report, but so far he had not heard from them. He said "I have no control over the Bureau of Mines, I cannot guarantee when they will report", but he hoped that it would be completed within two weeks.

He went on to say that he was not happy that Lewin's work had now turned into a research project on a new theory of structure and not a program for the definition of analytical procedures as we had all envisioned it to be. We agreed that we had both expected the McCrone and Lewin conference to settle the problem.

When I pressed for an assurance that the report would not be issued he said "it would be issued only over my dead body". He then discussed with me what he said was his problem of what to do with the report with respect to other manufacturers' products if our products were cleared on the basis of our work and presentation. He was afraid of being accused of favoritism to the large corporation, as they apparently were in the case of Bon Vivant Soup Company in relation to Campbell Soup. While he emphasized that this was his problem and not mine, he was interested in any comment that I would care to make. I suggested that since the controversy over Dr. Lewin's report centered around the analytical procedures used, that if our work (as I was confident it did) showed this to be invalid for our products, it obviously had to be invalid for the products of other manufacturers as well. I suggested that I thought it would be necessary to reanalyze the talcs by the accepted procedure that was worked out in our meeting.

Dr. Schaffner asked what I thought about tremolite and I responded that there was no evidence to implicate it as a carcinogen. He said he agreed with me and that they had searched the literature without success to find any report on the toxicity of tremolite. I said that I believed we had an article or two when tremolite had been used and found free of toxic effects (including carcinogenicity). I said that I would forward any references we had to him and he said that would be very helpful.

Dr. Schaffner then switched the subject to that of toxicity of talc per se. He said that there was pressure on the F. D. A. with respect to banning talc. When I asked if these pressures were generalized or if he could give specific samples he quoted from a

- 3 -

Meeting November 1, 1972
with Dr. Schaffner - FDA

December 13, 1972

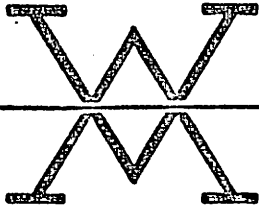
letter from a Mr. Fred C. Hart of the Department of Air Resources in New York City. The letter dealt with the use of talc containing asbestos in packaging materials and food additives and recommended its banning. The reasons given were some that we have heard before, mainly inuendo without any real facts to back them up. The letter further suggested that cosmetics probably should be included in the ban as well. (Dr. Nash would you please check to see if we can get a copy of Mr. Hart's letter the one dated September 18, 1972). Dr. Schaffner indicated that he believed it was on file with the Hearing Clerk. I told Dr. Schaffner we had a good deal of information on the freedom from toxicity on talc both from the literature and from some in house studies. He wanted to know if we would discuss this subject with some members of his staff and I agreed to do so. I told him that while much of this information was already organized into a report it would be better if we could postpone such a meeting until our work was completed and I guessed that this might be as early as two weeks but I couldn't be positive. I told him that should any emergency arise due to some incident or consumer pressure before our meeting with him, not to hesitate to call us. I said that Dr. Hildick-Smith would be prepared to discuss this subject with with them on a few hours notice.

Dr. Schaffner then concluded our meeting by suggesting that he call me in two weeks when he hoped to have his decision on Lewin's report finalized. If he did not have the necessary information from the Bureau of Mines and therefore could not give us the answer he would make an appointment for Mr. Smoyer and I to see Commissioner Edwards. I suggested that when he called we could perhaps set the date for our meeting to discuss the toxicity of talc. I thanked him for his providing the time for our meeting and we parted in a very friendly way.


R. A. Fuller

Exhibit 134

Callum RGD
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RESEARCH
AND
DEVELOPMENT

WALTER C. McCRONE ASSOCIATES, INC.

- SMALL PARTICLE PROBLEMS
- SOLID STATE CHEMISTRY
- ULTRAMICRO ANALYSIS
- CRYSTALLOGRAPHY
- MICROSCOPY

GENERAL OFFICE: 493 EAST 31st STREET • LABORATORIES: 449-493 EAST 31st STREET
CHICAGO, ILLINOIS 60616

PHONE: (312) 842-7100
CABLE: CHEMICRONE

12 October 1971

Dr. A. Goudie
Johnson & Johnson
Research Center
501 George Street
New Brunswick, New Jersey 08901

Dear Dr. Goudie:

This letter will cover the final reports on several groups of samples, namely, 228-P, the Feminine Spray, Medicated Powder and Shower to Shower group, and the two Italian talc samples which we have investigated with electron microscopy and electron diffraction.

If you have any further questions or comments please call us. It has been a pleasure working for you through these past few months and looking at the problems of talc and asbestos minerals. Thank you again for all of your courtesies and kindness.

Very truly yours,

Gene Grieger
Gene Grieger
Research Physicist

GG:aw

Ref: MA 2330

Billed monthly -
several - (many several) - pictures
sent without captions or mounting

11-11-71 aw MA 2347 and 2330

Dr. A. Goudie
Johnson & P. Johnson

Dear Dr. Goudie:

This letter will cover the final reports on several groups of samples, namely, 228-P, the Feminine Spray, Medicated Powder and Shower to Shower group, and the two Italian talc samples which we have investigated with electron microscopy and electron diffraction.

The 228-P appears to be very clean and very similar to the 344-L which we previously investigated. I believe that we can use all the data that we found on 344-L and apply it to 228-P as a general guide. The Feminine Spray, Medicated Powder, and Shower to Shower were also very clean. The Shower to Shower appeared to have a few more particles and fibers than the other two samples, however I think that might be due to possible contamination from the G-11. In the G-11 we did find two positively identified chrysotile fibers and some other fibers which at first glance appeared to be chrysotile, when you look at the electron diffraction pattern. I believe that most of the fibers in Shower to Shower which are suspect may come from the G-11. The Italian talc is probably some of the best talc that I have looked at to date. I think it is at least as good as the commercial product, 344-L and 228-P. There is one possible problem which I believe to be very slight and that is that there is a large mineral fiber in there which may tend to confust the issue of fiber content. We did identify this with electron diffraction as not being tremolite but I do believe that it may cause some anxiety in some circles.

In conclusion, with the exception of the G-11, I think all of these samples were quite clean with very low fiber content. I left out the comments on G-11

11-11-11 11:11 AM 11:11 AM 11:11 AM

11-11-11 11:11 AM 11:11 AM 11:11 AM

11-11-11 11:11 AM 11:11 AM 11:11 AM

This letter will cover the final reports on several groups of samples.

namely, 338-I, the Tanning Spray, Medication Powder and Shower's Shower

group, and the two Italian tile samples which we have investigated with

electron microscopy and electron diffraction.

The 338-P appears to be very clean and very similar to the 344-I which

we previously investigated. I believe that we can use all the data that we found

on 344-I and apply it to 338-P as a general guide. The Tanning Spray, Medication

powder, and Shower to Shower were also very clean. The Shower to Shower

appeared to have a few more particles than the other two samples.

However, I think that might be due to possible contamination from the G-11.

In the G-11 we did find two positively identified chrysotile fibers and some

other fibers which at first glance appeared to be chrysotile, when you look

at the electron diffraction pattern. I believe that most of the fibers in

Shower to Shower which are chrysotile may come from the G-11. The Italian

tile is probably some of the best tile that I have looked at to date. I think it

is at least as good as the commercial product, 344-I and 338-P. There is

one possible problem which I believe to be very slight and that is that there is

a large mineral fiber in there which may tend to confuse the issue of fiber content.

We did identify this with electron diffraction as not being a mineral fiber but I do

believe that it may cause some difficulty in some circles.

In conclusion, with the exception of the G-11, I think all of these samples

are quite clean with very low fiber content. I left out the 3 comments on G-11

from the report because I felt you might want to change your supplier or investigate your supplier, and this would only tend to confuse the issue perhaps with the FDA, should you later decide to use these reports with the FDA. If you have any further questions or comments please call us. It has been a pleasure working for you through these past few months and looking at the problems of talc and asbestos minerals. Thank you again for all of your courtesies and kindness.

VTY:GG

from the report because I felt you might want to change your supplier or investigate
your supplier, and this would only tend to confuse the issue perhaps with the FDA.
Would you later decide to use these reports with the FDA? If you have
any further questions or comments please call us. It has been a pleasure
working for you through these past few months and looking at the progress of this
and related materials. Thank you again for all of your cooperation and

kindness.

VTV:GG

We have, however, found ^{traces of} chrysotile in G-11, one of the additives to Shower-to-Shower, and this might be a possible source of these contaminant fibers.

Add
cut + Gaste master
add the above sentence
where the # is on sheet # 4

10. The Board of Directors of the Company has approved the issuance of the shares of common stock to the Company's employees, officers, directors, and consultants, and has authorized the Company to enter into an equity incentive plan for the purpose of attracting and retaining qualified personnel.

11. The Board of Directors of the Company has approved the issuance of the shares of common stock to the Company's employees, officers, directors, and consultants, and has authorized the Company to enter into an equity incentive plan for the purpose of attracting and retaining qualified personnel.

**FINAL REPORT ON SHOWER TO SHOWER, MEDICATED POWDER
AND FEMININE SPRAY**

Summary

We have examined samples of three Johnson & Johnson talc products, Shower to Shower, Medicated Powder and Feminine Aerosol Spray. These products all seem to be quite clean, and we did not find any fibers of the asbestiform minerals in any of them: in particular, there are no bundles of chrysotile fibers and only in rare cases did we find any fibers suspect on the basis of morphology. The maximum number of suspect fibers which we found in any sample was two, in the Shower to Shower. There is a possibility of contamination by approximately one fiber in our lab and probably some contamination in the processing just from airborne fibers which get into the product during the grinding and mixing procedures.

Introduction

McCrone Associates has examined the appearance and fiber content of samples of Johnson & Johnson Shower to Shower, Medicated Talc Powder and Feminine Aerosol Spray. The electron microscopy and electron diffraction methods used are described in a previous report to Johnson & Johnson, MA2330-1.

Final Results of Examination

Feminine Spray

The Feminine Spray sample showed talc plate sizes which are considerably smaller than those particle sizes in the other talc products.

The fiber content in this sample of Feminine Spray seems to be quite low, and we found very few examples of rolled talc or other fibers. We found one unknown mineral fiber which we considered at first to be chrysotile, but, after a careful comparison of our standard chrysotile electron diffraction patterns and the unknown mineral pattern, we decided that it was not chrysotile. This fiber has a central coring similar to chrysotile but shows a diffraction pattern different from chrysotile. This strong morphological similarity might have led to confusion without the use of electron diffraction and chrysotile standards.

A few talc fibers and some other small mineral fibers were identified with electron diffraction. In addition, we found a fiber from which we could not get an electron diffraction pattern. It did not appear to have a chrysotile structure but might possibly be calcium phosphate or sodium sesquicarbonate.

Medicated Powder

The Medicated Powder is very similar in cleanliness to the Feminine Spray Powder. The additive "Microcell" appears to be a fine web-like structure, in some cases platy which appears very similar to crinkled newspaper when viewed from the top.

None of the several chemical additives which we found appeared to be fibrous: several orthorhombic, cubic, or perhaps tetragonal crystals might be calcium silicate.

We found few examples of fibrous talc and only one fiber which could be considered suspect because of its central coring. This suspect fiber gave an excellent electron diffraction pattern which, in our opinion, differs from chrysotile both in d values and intensity relationships. It could be hydromagnesite, halloysite or a rolled silicate. In addition to the suspect fiber we found examples of what appeared to be sodium sesquisitrate or a chemical very similar to it: the coring was not quite as obvious and it did give a slight electron diffraction pattern; there is a strong possibility that this is calcium phosphate or one of the ingredients added to the powder to give its medicated quality.

Shower to Shower

The fiber content of Shower to Shower is quite low in comparison to previous samples which we have investigated and is predominantly rolled talc, I estimate it to be on the order of 0.001% and definitely no greater than 0.005%. We found three suspect fibers. Of these, two were found in one field and probably have the same source, very possibly contamination. Because they were covered by a talc plate, it was impossible to get electron diffraction

the same general characteristics, but it still is questionable whether they are chrysotile. We have, however, found traces of chrysotile in G-11, one of the additives to Shower to Shower, and this might be a possible source of these contaminant fibers. The third fiber is quite small and in a field surrounded by small plates of talc. We have compared its electron diffraction pattern with those of talc and chrysotile and it does not appear to be either of the two. It is similar to chrysotile only insofar as it has an apparent coring of the sample.

In the remainder of the sample, we found few talc shards, i. e., small fragments of talc broken from larger plates which give talc patterns in most cases but which appear as fibers. There is some rolled talc and some other mineral fibers which we have not been able to identify with electron diffraction but which do not have any of the characteristics of amphiboles or chrysotile. As in the other two Johnson & Johnson products, we found several examples of fibers which have all of the general characteristics of sodium sesquicarbonate, although they do not produce electron diffraction patterns. They generally occur in bundles and are not limited to single fibers as is chrysotile. The bundles of fibers, however, are quite random in orientation and seem to be almost a woven or intertwined structure.

Observation

In regard to the suspect fibers, many types of mineral fibers have a core similar to chrysotile, but their electron diffraction patterns identify them as other minerals. However, we cannot always obtain electron diffraction patterns from suspect fibers because they may have slightly different mineralogical structures which do not lead to strong electron diffraction patterns and/or their pattern may be masked by the major mineral species present in the sample.

Exhibit 135

Exhibit 73



mcCrone environmental services, inc.
200 OAKBROOK BUSINESS CENTER
5500 OAKBROOK PARKWAY
NORCROSS, GA 30093 • 404-449-8461

29 April 1986

Windsor Minerals, Inc.
P. O. Box 680
Windsor, Vermont 05089

RECEIVED
MAY 2 1986

Attention: Mr. Roger N. Miller, President

W. M. I.

Re: McCrone Project No. ME-2275

Dear Mr. Miller:

Under your Purchase Order WS-0503 we received eleven (11)
talc samples for asbestos analysis. The samples were identified
as follows:

WMI 85-50	WMI 85-54	WMI 85-59	WMI 85-62
WMI 85-51	WMI 85-56	WMI 85-60	WMI 85-63
WMI 85-52	WMI 85-58	WMI 85-61	

Examinations by transmission electron microscopy resulted in
no quantifiable amounts of asbestiform minerals in the samples.
Thank you for consulting McCrone Environmental Services, Inc.

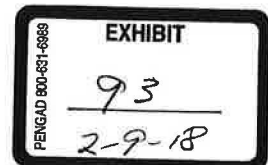
Sincerely,

Thomas Kremer
Thomas Kremer
Electron Microscopist
James R. Millette
James R. Millette, Ph.D.
Manager, Laboratory Services

TK/JRM/mcs

cc: 1) Windsor Minerals, Inc.
Windsor VT
1) Mr. Roger N. Miller, President

a subsidiary of walter c. mcCrone associates, inc.
2820 SOUTH MICHIGAN AVENUE • CHICAGO, ILLINOIS 60616 • 312-842-7100

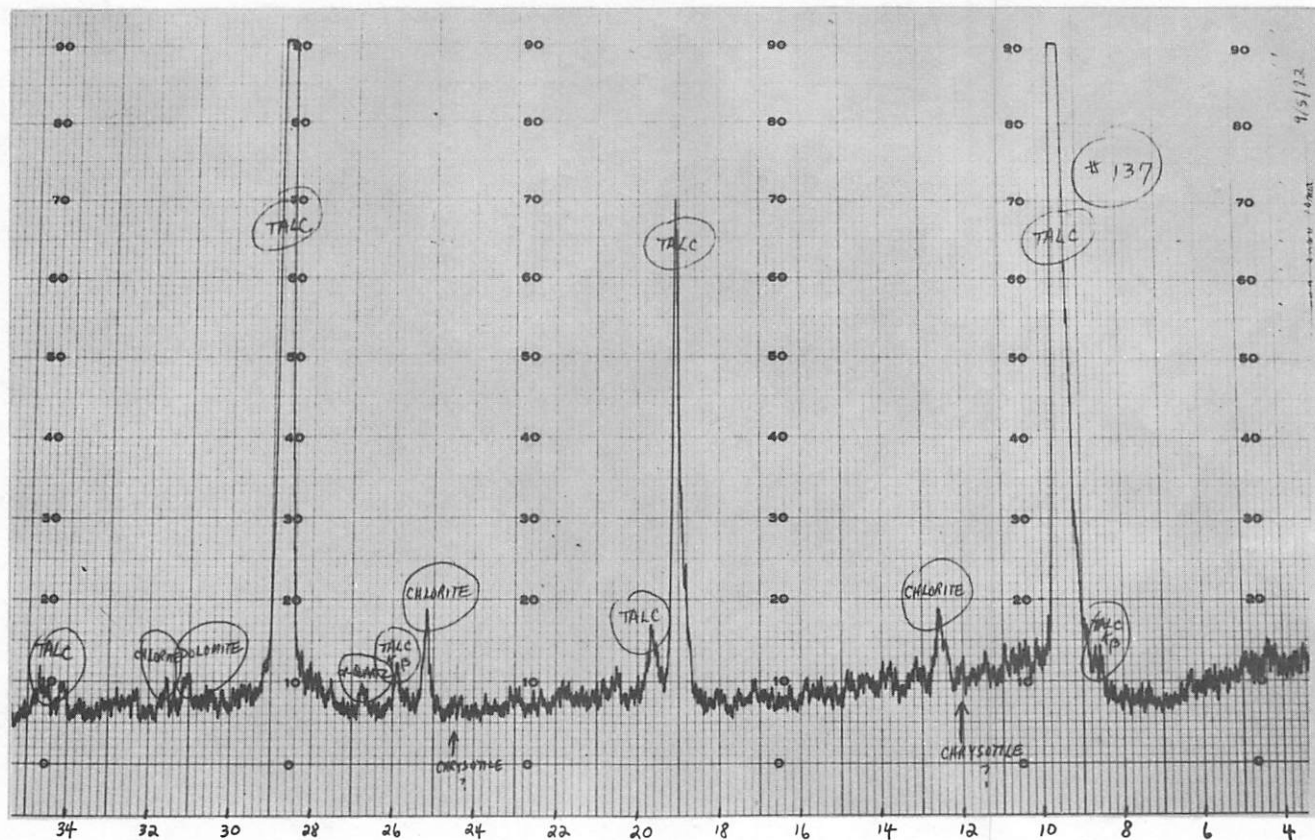


J&J-0044937

Exhibit 136

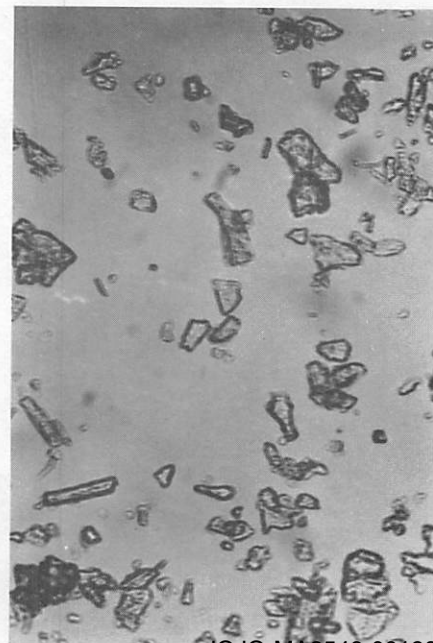
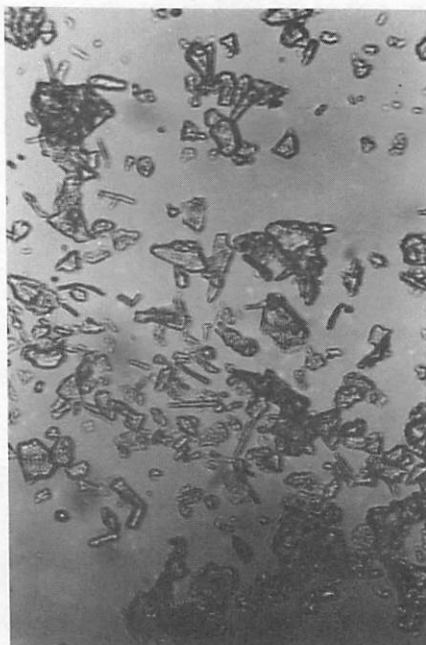
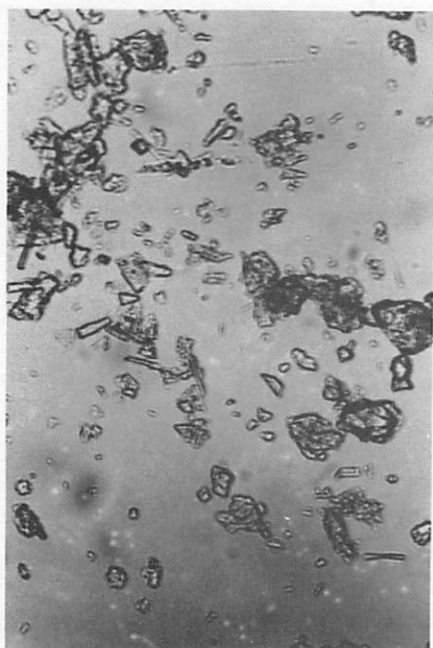
SAMPLE NO. 137.

X-RAY DIFFRACTION PATTERN *Lot No*
0709 XY

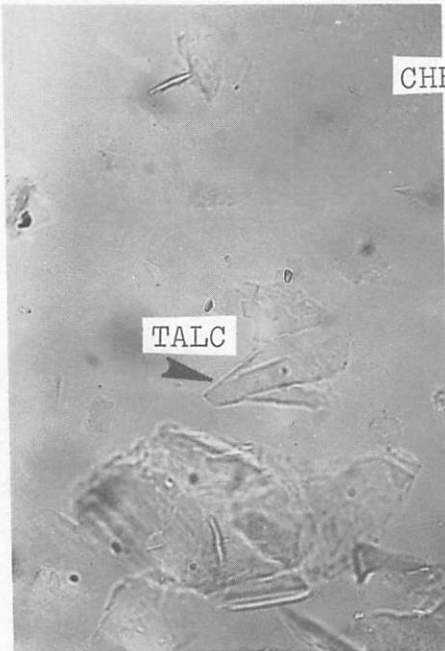
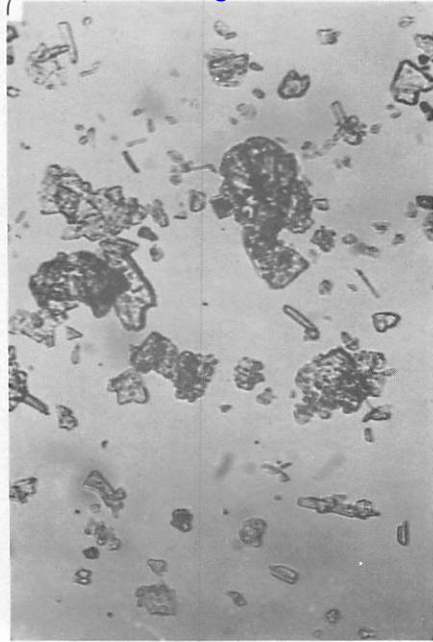
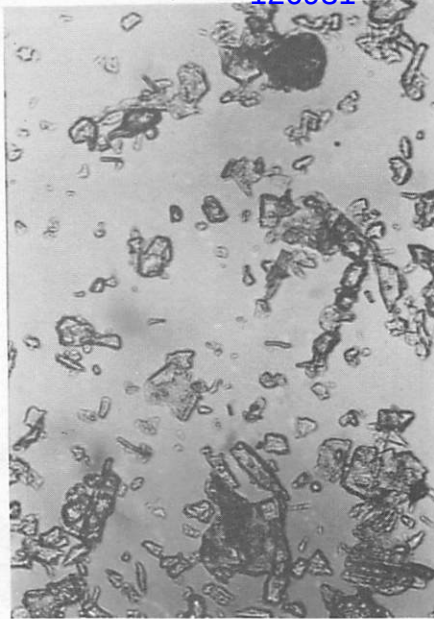
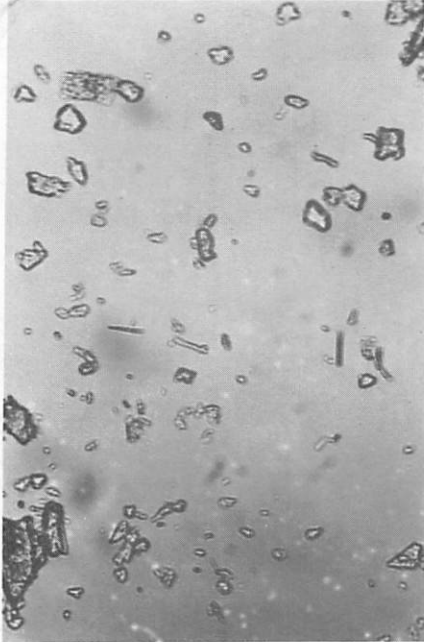


Analytical Results: TALC 89%; CHLORITE 4%; α -QUARTZ 3%; DOLOMITE 2%;
CHRYSTOTILE 2%

Below: PHOTOMICROGRAPHS OF DRY POWDER NO. 137

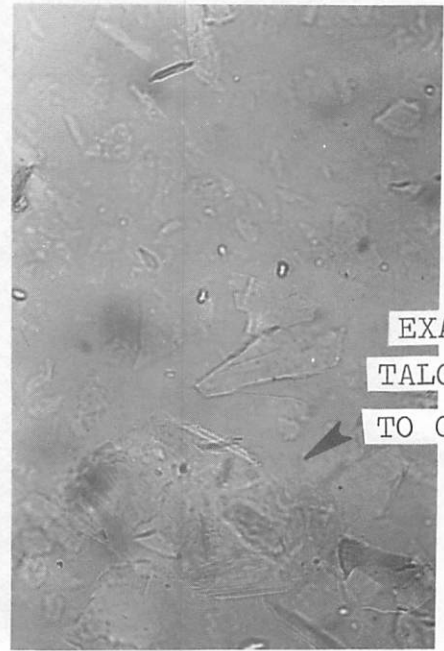
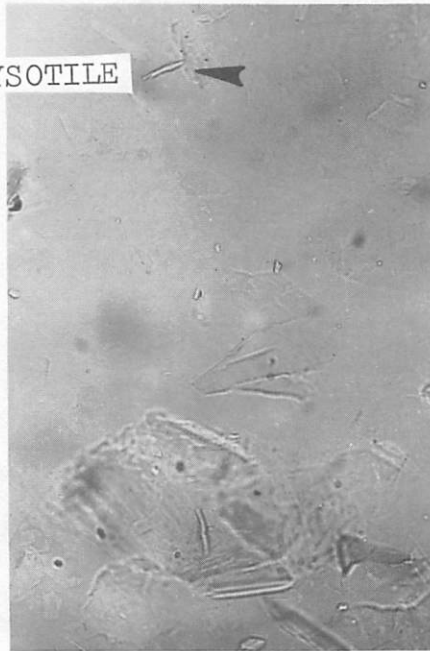


DRY POWDER, SAMPLE NO. 137



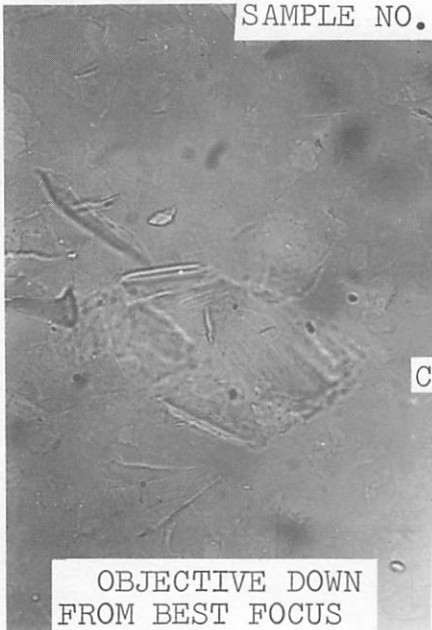
CHRYOTILE

TALC

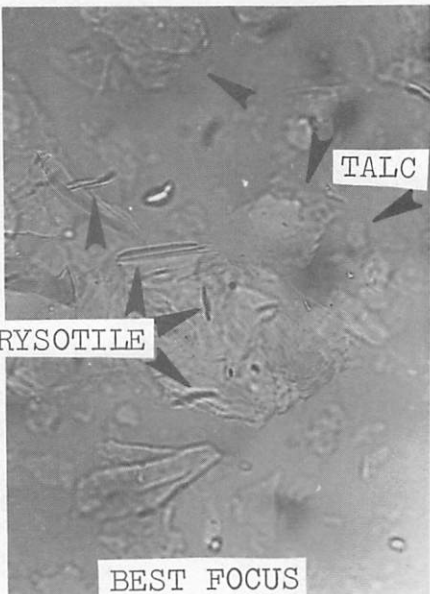


EXAMPLES OF
TALC ALTERING
TO CHRYOTILE

SAMPLE NO. 137 IN IMMERSION LIQUID OF $n = 1.580$



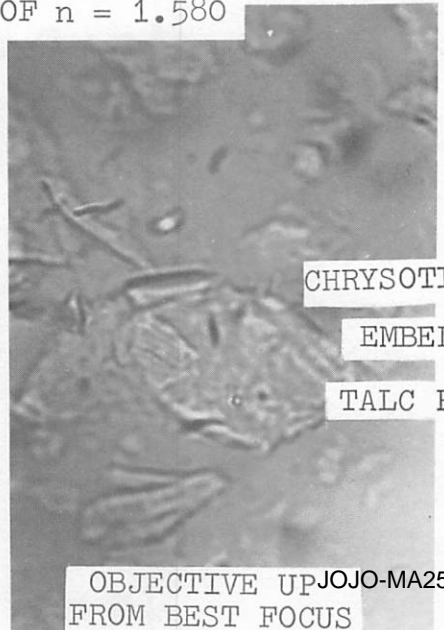
OBJECTIVE DOWN
FROM BEST FOCUS



TALC

CHRYOTILE

BEST FOCUS

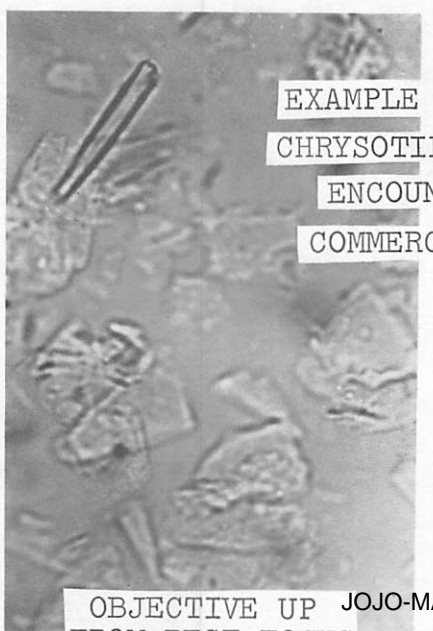
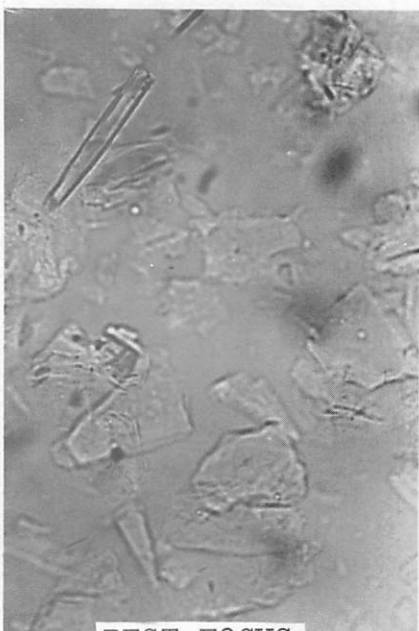
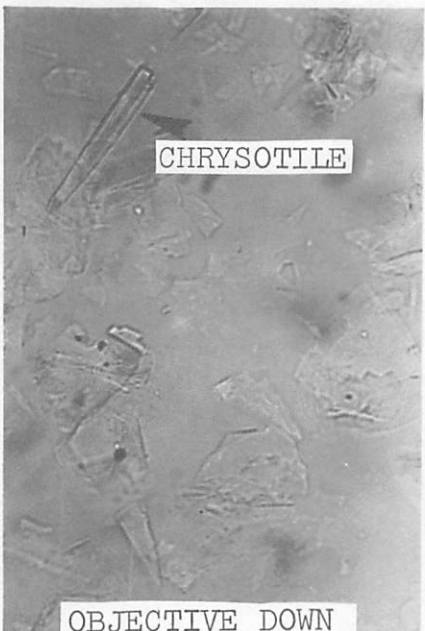
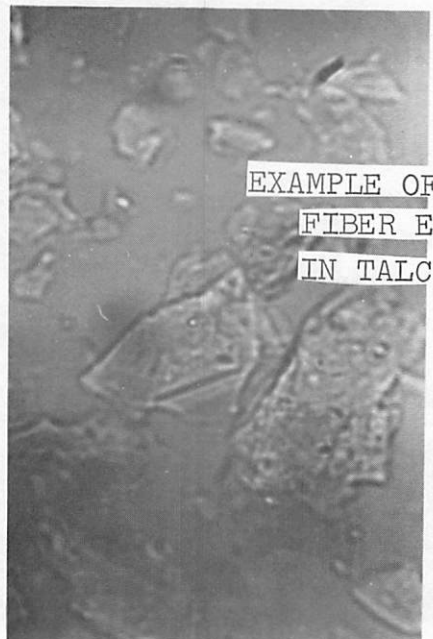
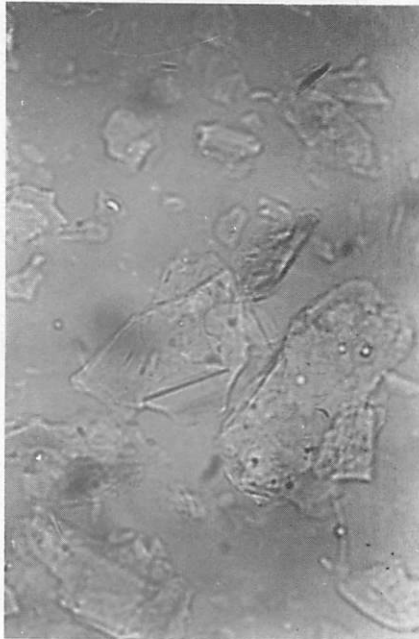
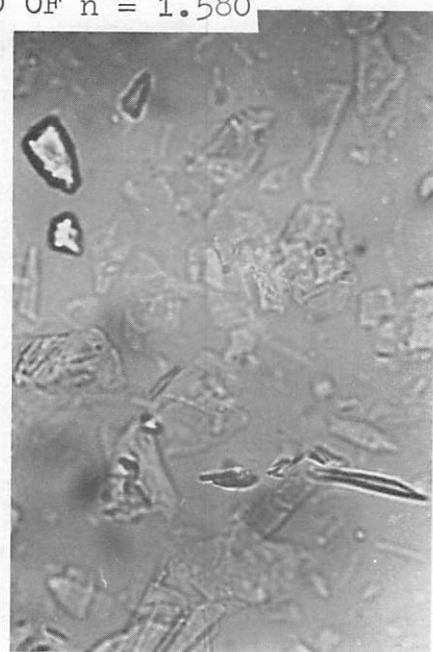
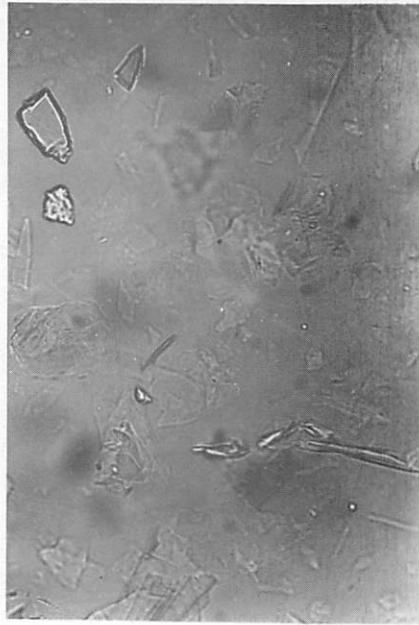
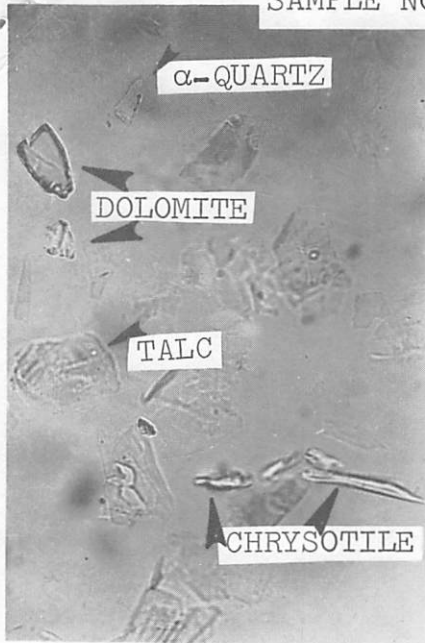


CHRYOTILE FIBERS
EMBEDDED IN
TALC PARTICLES

OBJECTIVE UP
FROM BEST FOCUS

JOJO-MA2546-00139

SAMPLE NO. 137 IN IMMERSIION LIQUID OF $n = 1.580$



OBJECTIVE DOWN
FROM BEST FOCUS

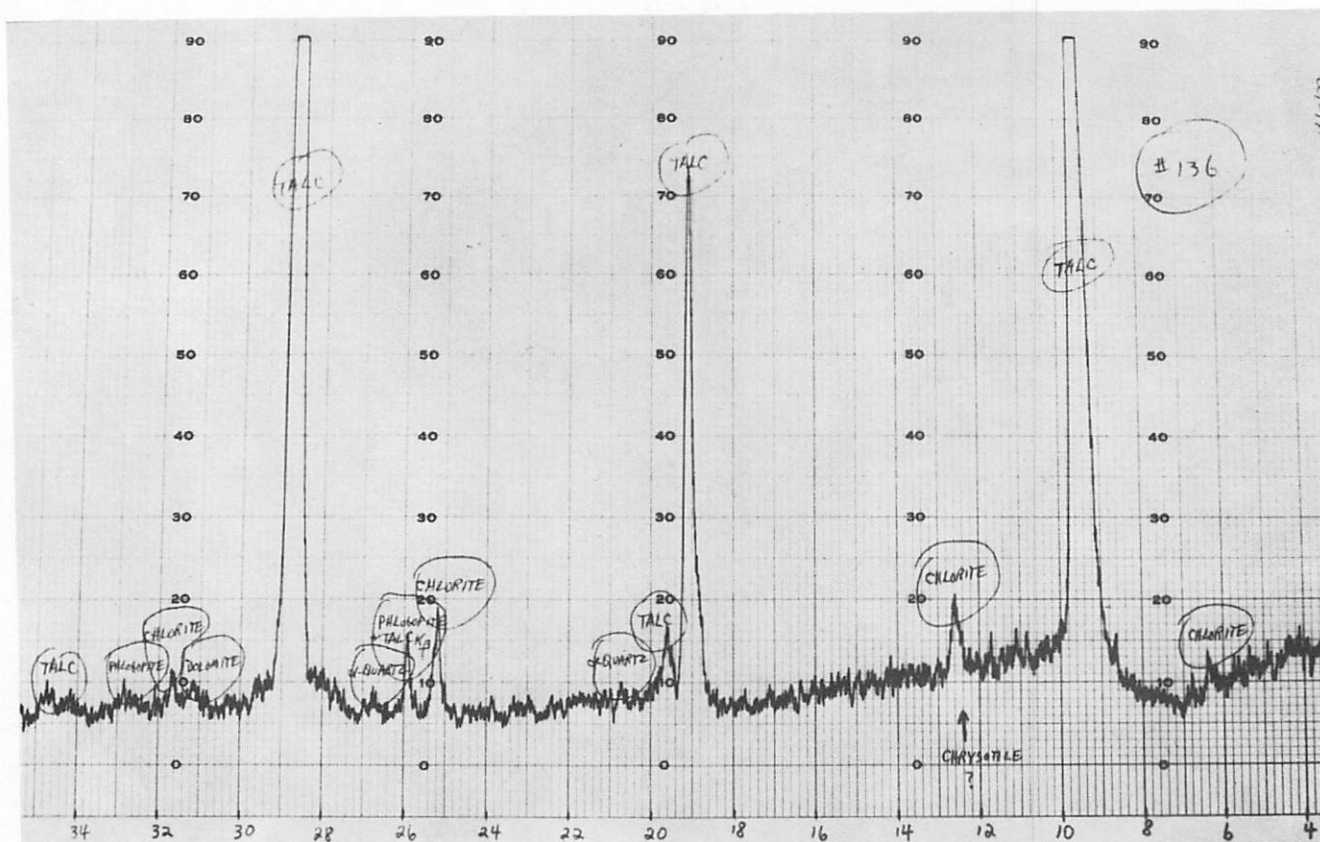
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OBJECTIVE UP
FROM BEST FOCUS

JOJO-MA2546-00140

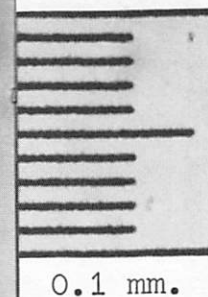
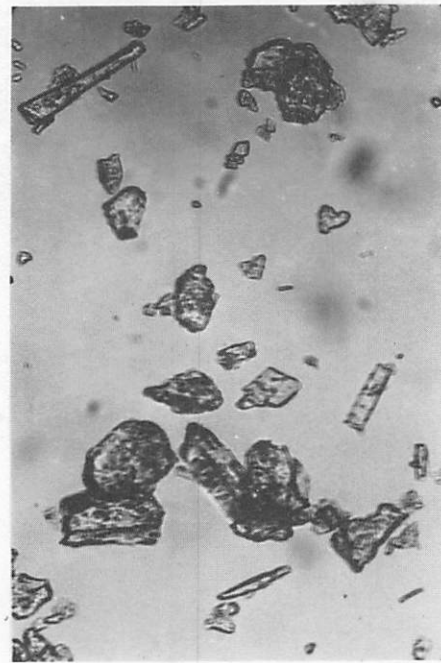
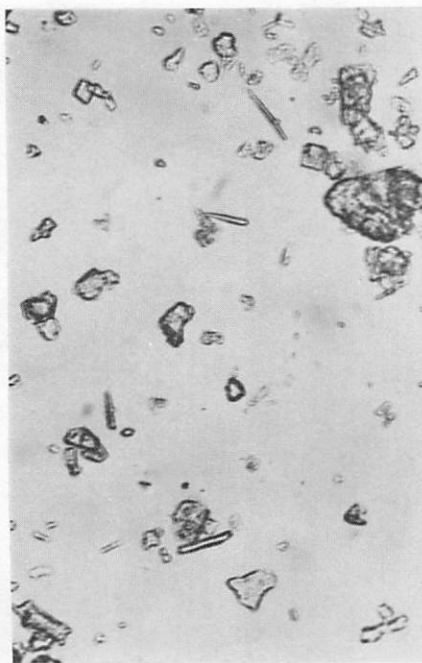
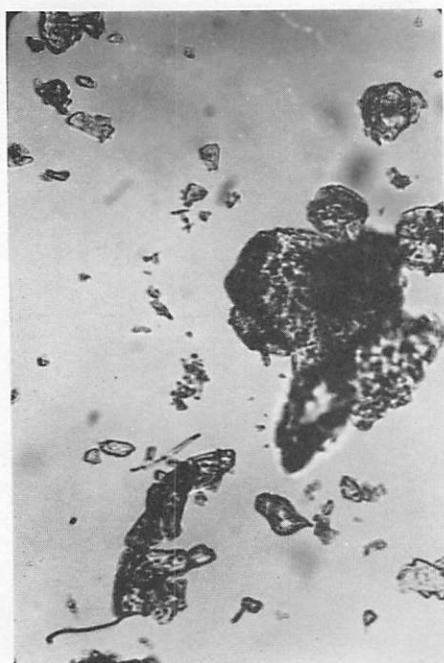
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X-RAY DIFFRACTION PATTERN

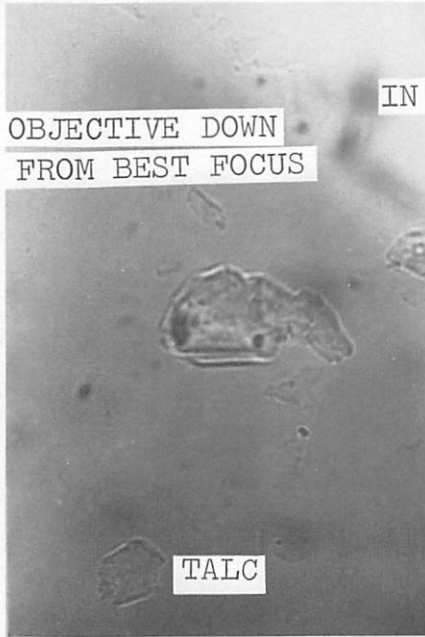
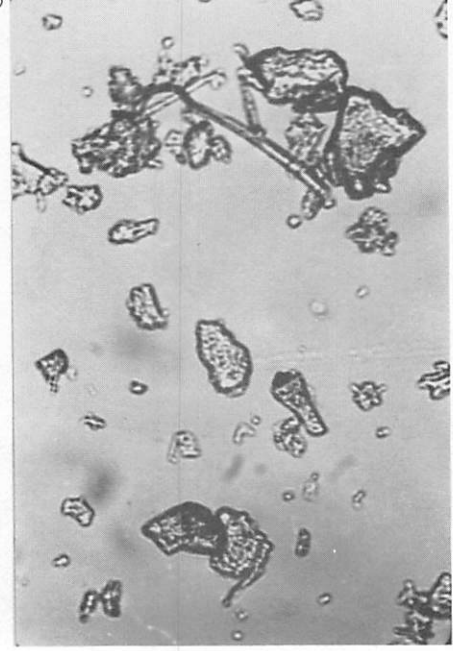
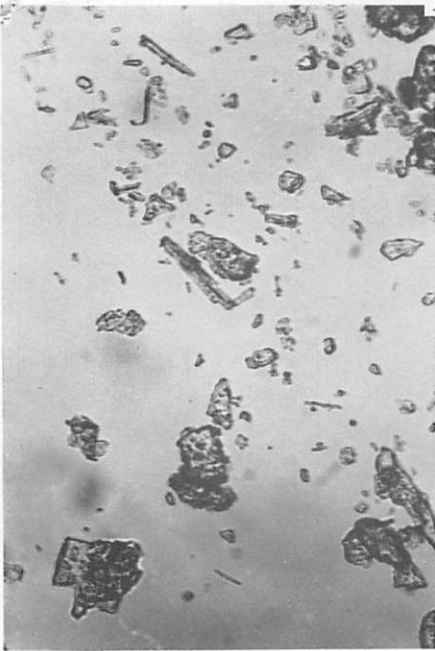


Analytical Results: TALC 87%; CHLORITE 4%; PHLOGOPITE 3%;
α-QUARTZ 2%; DOLOMITE 2%; CHRYSOTILE 2%

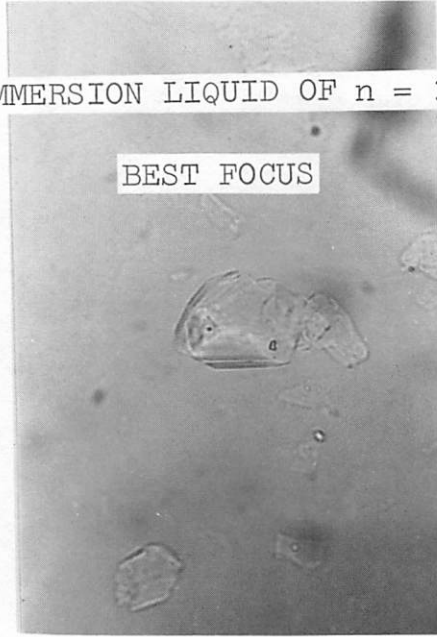
PHOTOMICROGRAPHS OF DRY POWDER NO. 136



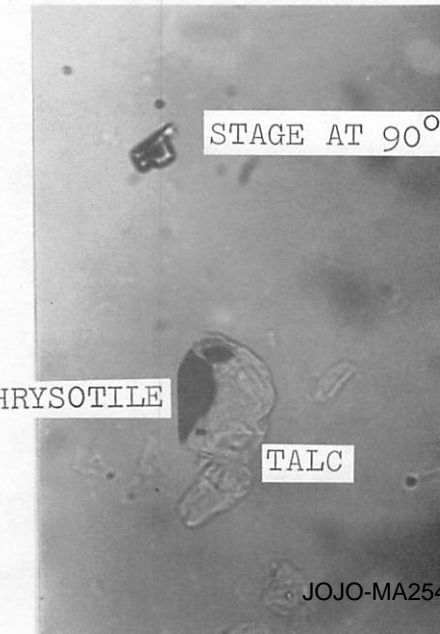
126934
DRY POWDER, SAMPLE NO. 136

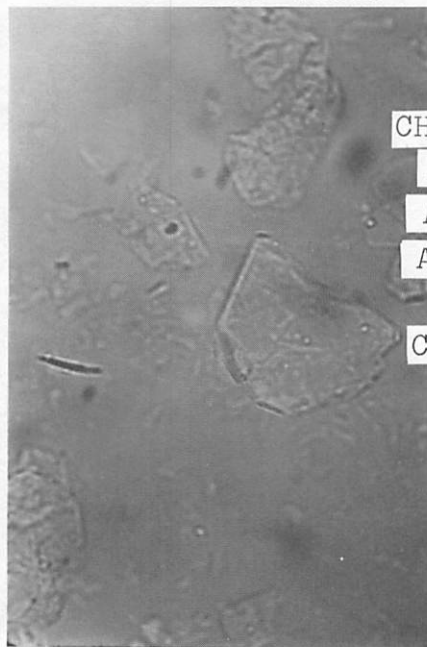
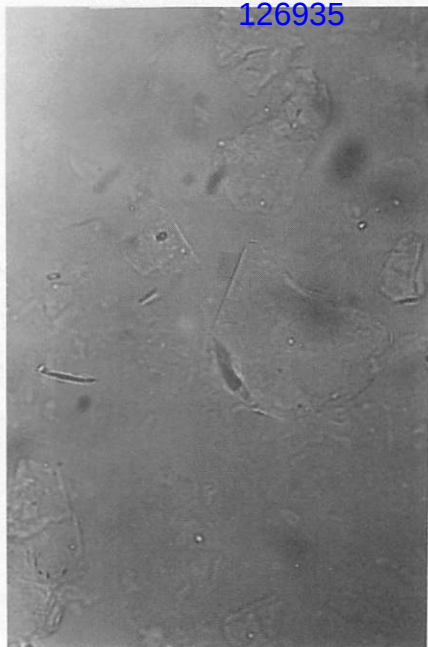
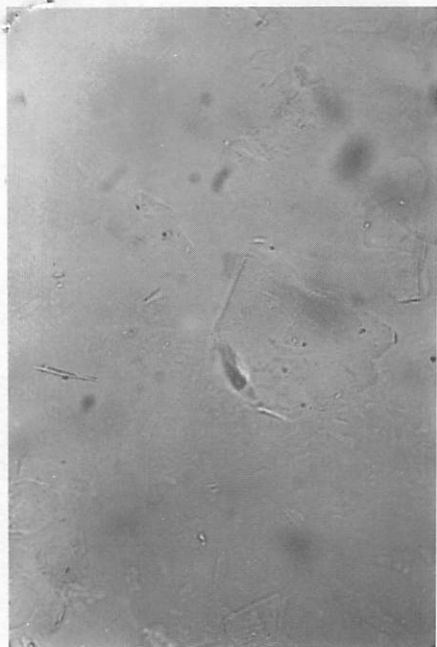


IN IMMERSION LIQUID OF $n = 1.580$



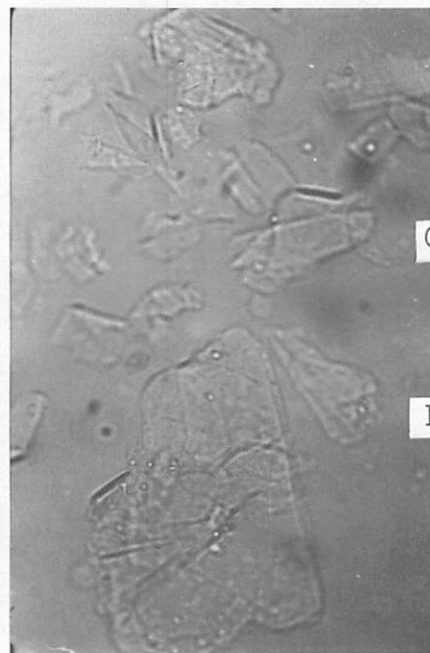
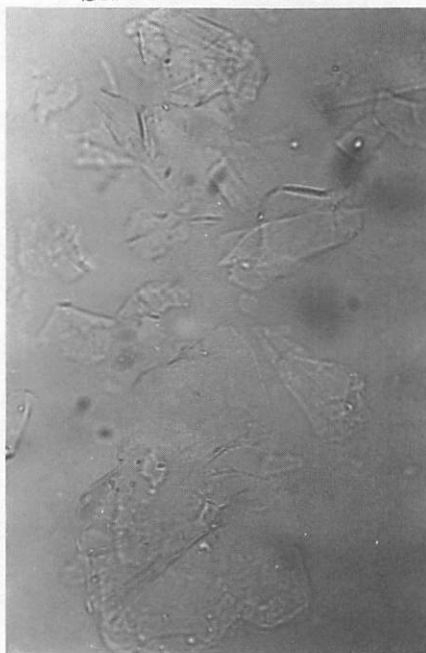
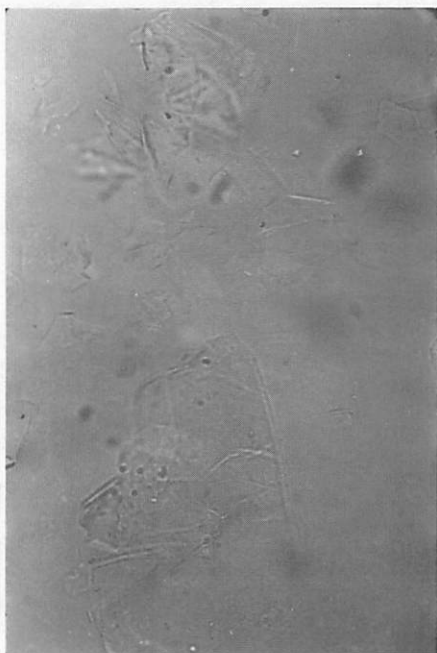
TALC
ALTERING
TO
CHRYSTILE



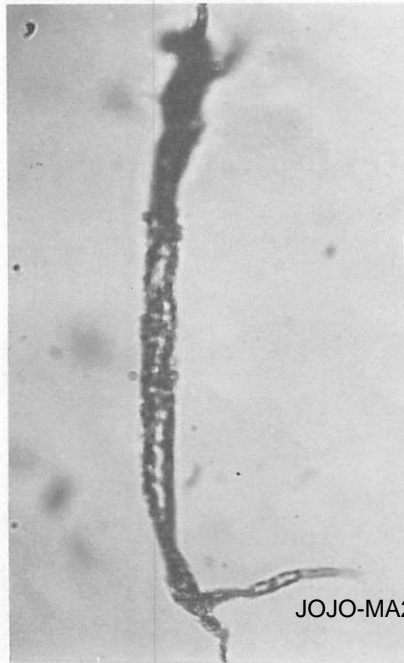
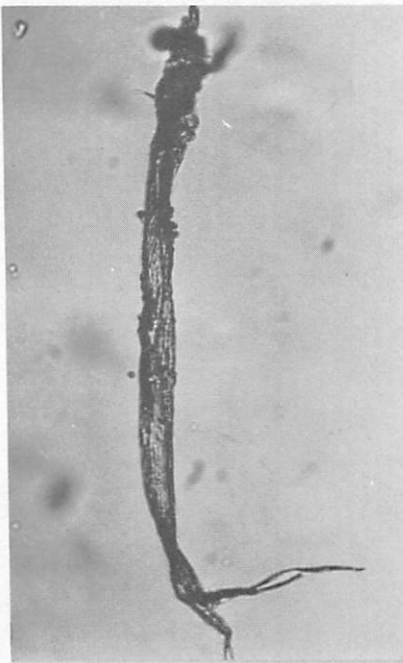
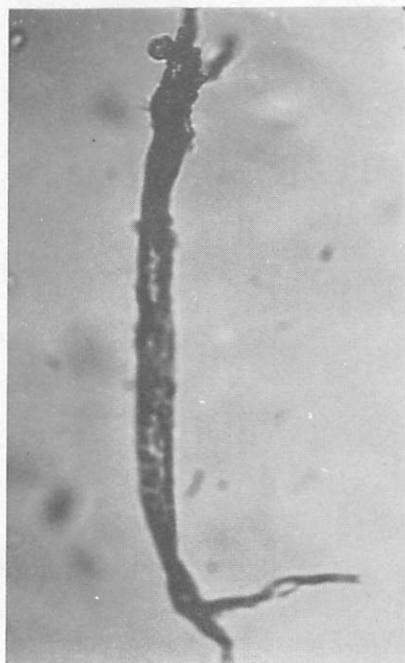


CHRYSTILE
FIBERS
AND TALC
ALTERING
TO
CHLORITE

SAMPLE NO. 136



CHRYSTILE
FIBERS
WITHIN
TALC
PARTICLES



ORGANIC
FIBER

Transmission Electron Microscope

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Particle settling in a swirl tube was used for obtaining the dispersion of "tale" on 200 mesh microscope grids. Lewin and Shower to shower were collected.

Lewin

Roughly 900 grid squares were scanned in the T.E.M. at moderate magnification. Five fibrous particles were found which gave electron diffraction patterns unmistakably *crysotile asbestos*. One highly suspect particle gave a noncrysotile diffraction pattern. The particles were generally ~~one~~ less than 30 microns in length and had the typical fiber structure. No bundle branch and join was however seen.

Shower to Shower.

~~Roughly~~ Approximately 2100 grid squares were examined. Numerous examples of fibrous structures were seen. Electron diffraction of these fibers showed no resemblance to *crysotile asbestos* patterns. Three clear examples were found of serpentine material and which gave perfect *crysotile* patterns.

transmission electron microscope

the following line of text

Particle < 200 nm in a small tube was

used for obtaining the composition of "fat"

on AOS were analyzed with a scanning

electron microscope.

Results

Approximately 100 grid squares were

examined in the TEM at high voltage magnification.

Five fibrous particles were found which

gave electron diffraction patterns unambiguously

typical of asbestos. One highly suspect

particle gave an inconclusive diffraction

pattern. The particles were generally less

than 30 nm in length and had the typical

fibrous structure. No sample damage was

observed.

Slower to slower

Approximately 200 grid squares

were examined. Numerous examples of

fibrous structures were seen. Electron

diffraction of these fibers showed no evidence

to implicate asbestos fibers. These glass

samples were found of significant material

Two long fibers were found singly and two others were in the same grid square and apparently in close association with a talc structure. These fibers showed clear ~~fibrous~~^{filamented} structure at high magnification.

Total Concentration Calculation (Shaw to Shaw)

Prints of the micrographs were cut to estimate the relative ~~area~~ area of asbestos and ~~non~~ talc ~~areas~~. One fifth of one square contained inconvertible asbestos, while approximately 1550 squares were covered with talc. This yielded an area percentage of one part in 7500 or roughly one one hundredth of one percent.

The total concentration of all "fibers" was near .one percent.

Summary: Neither scanning microscopy alone or aided by X-ray energy dispersive element detection can unequivocally identify erosive asbestos in concentration of a few percent. No elemental tag exists to discriminate as ~~fibers~~ from other fibrous minerals present. T.E.M. with electron diffraction shows less than ~~0.01%~~ .01%
This E Hutchinson, Univ of Minnesota

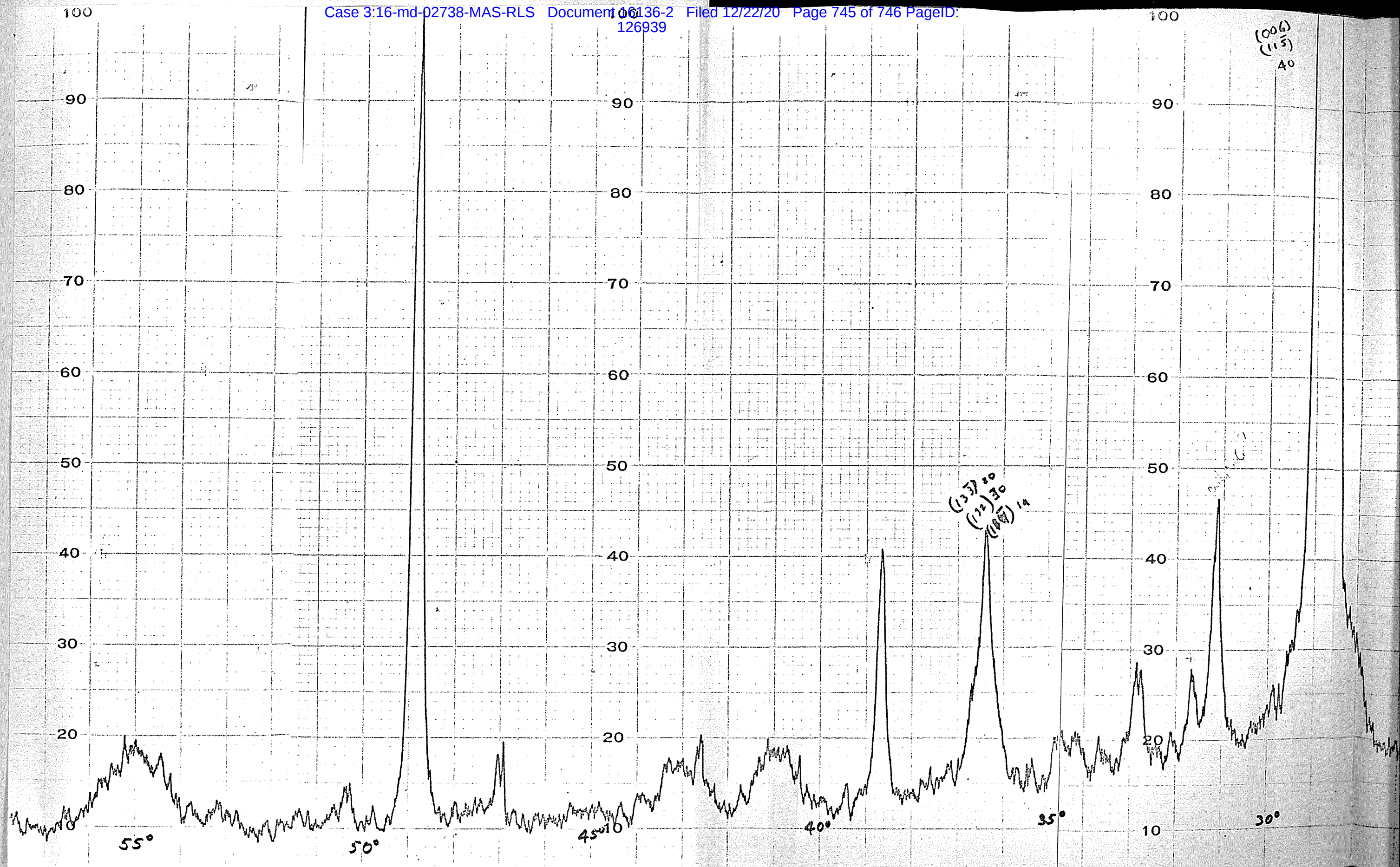


Figure 20 Full diffractometer trace of Sample No. 16

